

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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IN RE INSYS THERAPEUTICS, INC.  
SECURITIES LITIGATION

Civil Action No. 1:17-cv-01954-PAC

**SECOND AMENDED CLASS ACTION COMPLAINT  
FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS**

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Court-appointed Lead Plaintiff Michael Robson (“Plaintiff”) brings this action pursuant to §§ 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5), on behalf of all persons or entities other than Defendants (defined below) who purchased or otherwise acquired the securities of Insys Therapeutics, Inc. (“Insys” or the “Company”) between May 7, 2015 and March 15, 2017 (the “Class Period” and collectively the “Class”).

Plaintiff’s information and belief, concerning matters other than himself and his own acts, are based on the investigation of his undersigned Lead Counsel, which included, among other things, review and analysis of: (i) Insys’s public filings with the U.S. Securities and Exchange Commission (“SEC”); (ii) Insys’s other public statements, including in press releases and conference calls; (iii) discussions with accounting experts; (iv) reports of securities and financial analysts, news articles, and other commentary and analysis concerning Insys and the industry in which it operates; and (v) review of pertinent court filings.

Lead Counsel’s investigation into the matters alleged herein is continuing, and many relevant facts are known only to, or are exclusively within, the custody or control of the Defendants. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

#### **SUMMARY OF THE ACTION**

1. This securities fraud class action is predicated upon an extensive and pervasive fraud, orchestrated by the most senior executives of Insys, who sought to conceal the Company’s declining revenues from Subsys, its exclusive source of revenue, in the face of intense regulatory scrutiny and resulting withdrawal of Insys’s primary customers – third-party government payers and private insurance companies.

2. Prior to the Class Period, Insys reported double-digit revenue growth from the sale of Subsys. Insys was only able to report such growth, however, as a result of the Company's widespread off-label marketing and kickback scheme that induced third-party payers into authorizing insurance coverage for off-label prescriptions of Subsys. After this scheme was exposed beginning in the fall of 2014, third-party payers began to substantially reduce reimbursement for off-label use of Subsys and prescriptions went down, so distributors began ordering less product and returning unused product.

3. In order to conceal the significant decline in Subsys revenue and increased product returns, which allowed Insys to report sustained revenue growth, Defendants embraced an admitted "*tone at the top*" to artificially inflate Insys's revenues by prematurely recording revenue before it was earned and understating the Company's sales allowance by improperly recording rebate obligations to third-party payers and other product sales allowances. Insys's revenue and sales allowance levels served as the primary indicator of the strength of the Company's present and future revenue stream, and the market looked to this metric to assess the Company's value. As a result of this scheme, Insys falsified no less than three years of financial statements and would be required to restate no less than six separate quarters of financial reports.

4. Yet simultaneously, to reassure investors of Insys's continued revenue growth and the integrity of the Defendants' sales allowance metrics, Defendants repeatedly represented throughout the Class Period that Insys actively monitored the rate of Subsys prescriptions on a daily basis, in real-time, admittedly had access to inventory levels at its biggest wholesale customers, and also actively communicated with third-party payers to obtain prior authorization and insurance coverage for invariably expensive Subsys prescriptions. Further, Defendants falsely

represented that Insys maintained adequate internal controls over financial reporting and prepared its financial statements in accordance with generally accepted accounting principles (“GAAP”).

5. On March 15, 2017, Insys announced that the Company had to delay the release of its financial results for the fourth quarter and full year 2016 because the Insys Audit Committee was investigating “[t]he Company’s processes related to estimation of, and increases to, certain sales allowances recorded during 2016, with a potential reduction of 2015 net revenue and pre-tax income not expected to exceed \$5 million, as well as extended payment terms offered to certain customers during the third quarter of 2016.”

6. Upon this news, the price of Insys common stock declined from a closing share price of \$10.55 on March 15, 2017 to \$10.06 at close on March 16, 2017, a loss of 4.64 percent, on heavy trading volume that was 37.4% higher than the prior day. In contrast, on March 16, 2017 the Nasdaq US Smart Pharma Index was up 1.6%.

7. Following the March 15 announcement, on March 31, 2017, Defendants reaffirmed Insys’s March 15 announcement that effectively informed investors the Company was engaging in material accounting manipulations relating to the recording of revenue and sales allowances. Specifically, Insys disclosed that the Audit Committee had concluded its investigation and determined that the Company’s previously issued interim unaudited consolidated financial statements for the quarters ended September 30, June 30, and March 31, 2016 and 2015 should no longer be relied upon and that those financial statements would be restated due to the identification of “*material*” errors related to Insys’s accounting for certain of its product sales allowances.

8. Plaintiff seeks to recover damages as a result of the alleged fraud.

**JURISDICTION AND VENUE**

9. The federal law claims asserted herein arise under §§ 10(b) and 20(a) of the Exchange Act, 15 U.S.C. § 78j(b) and § 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.

10. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and § 27 of the Exchange Act, 15 U.S.C. §78aa. In connection with the acts, conduct and other wrongs alleged herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the U.S. mails, interstate telephone communications and the facilities of the NASDAQ Global Select Market (“NASDAQ”) (a national securities exchange located in this District). During the Class Period, Insys’s common stock traded on the NASDAQ under the symbol “INSY.”

11. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) and § 27 of the Exchange Act because substantial acts in furtherance of the illegal conduct alleged herein occurred in this District. Many of the acts complained of herein, including the dissemination of materially false and misleading statements and reports prepared by or with the participation, acquiescence, encouragement, cooperation or assistance of Defendants occurred, at least in part, in this District.

**THE PARTIES**

**I. Lead Plaintiff**

12. Lead Plaintiff Michael Robson, as previously set forth in his certification supporting his motion for appointment as Lead Plaintiff, incorporated by reference herein, purchased Insys securities at artificially inflated prices during the Class Period and has been damaged thereby.

## **II. Defendants**

### **A. Insys Therapeutics, Inc.**

13. Insys is a corporation organized and existing under the laws of the State of Delaware with its principal executive offices located at 1333 South Spectrum Boulevard, Suite 100, Chandler, Arizona, 85286. The Company represents that it is a specialty pharmaceutical company that develops and commercializes supportive care products primarily designed to assist patients with pain management attributable to their disease, treatments, or therapies. Insys's pipeline and only marketed product is Subsys, a "rapid onset opioid" delivered through a sublingual spray. Subsys was approved by the FDA in January 2012 *only* to treat breakthrough cancer pain ("BTCP") in opioid tolerant patients, i.e. gravely ill cancer patients already receiving around-the-clock opioid pain medication.

### **B. The Individual Defendants**

14. Individual Defendant Michael L. Babich was the Chief Executive Officer ("CEO") of Insys and a director of Insys's wholly-owned subsidiary, Insys Pharma, Inc., from March 2011 until November 11, 2015. Between March 2007 and March 2011, Babich was the Company's Chief Operating Officer. As noted by the Company's co-founder and Individual Defendant Dr. John N. Kapoor ("Kapoor"), Babich helped transform the Company "from a development stage enterprise to a successful, commercial, publicly-traded company known for its development of a leading commercial product, Subsys." Babich abruptly resigned from his role as CEO of Insys, effective immediately, on November 5, 2015. On December 8, 2016, Defendant Babich was arrested and charged with nationwide (i) racketeering, (ii) mail fraud conspiracy to defraud patients of honest services, (iii) conspiracy to commit health care fraud by engaging in kickback schemes in violation of the federal Anti-Kickback Statute, and (iv) conspiracy to defraud insurers and pharmacy benefit managers ("PBMs") to obtain authorization of off-label Subsys prescriptions.

The indictment alleged that Babich and former Vice President of Sales Alex Burlakoff had “led a nationwide conspiracy to bribe medical practitioners to unnecessarily prescribe a fentanyl-based pain medication and defraud healthcare insurers.”<sup>1</sup> Babich’s wife, Natalie Levine, pleaded guilty in July 2017 to federal charges that she participated in the Insys kickback scheme that defrauded federal healthcare programs.

15. Babich participated in the management and day-to-day operations of the Company and had actual knowledge of confidential proprietary information concerning Insys and its business, operations, growth, financial statements, and financial condition. Because of his position of control and authority, his ability to exercise power and influence with respect to Insys’s course of conduct, and his access to material inside information about Insys during the Class Period, at all relevant times, Babich was a controlling person of Insys within the meaning of § 20(a) of the Exchange Act. As alleged herein, during the Class Period, Babich made materially false and misleading statements concerning the Company’s finances, operational and compliance policies.

16. Individual Defendant Kapoor was the President and CEO of Insys from November 5, 2015 until January 9, 2017. Kapoor is also the Company’s founder, controlling stockholder, and former Chairman of the Board. In a March 3, 2015 Form 8-K, Insys disclosed that it had entered into a consulting agreement with Kapoor, paying him an additional \$300,000 annually “to compensate Dr. Kapoor for his ongoing time and contribution to the company.” Kapoor assumed the positions of President and CEO following the resignation and subsequent arrest and criminal indictment of, among others, Babich and Burlakoff.

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<sup>1</sup> See First Superseding Indictment, *United States v. Babich et al.*, No. 1:16-cr-10343-ADB (D. Mass. filed Oct. 24, 2017) (“Massachusetts Indictment” or “Mass. Indictment”).

17. Insys emphasized the critical role of Kapoor as the Company's President, CEO, and controlling stockholder in SEC filings and press releases filed or issued throughout the Class Period. For example, the Company's Annual Report on Form 10-K for the 2016 fiscal year, filed with the SEC on April 3, 2017 ("2016 Annual Report") acknowledged that, because Kapoor beneficially owns or controls 67% of Insys's outstanding common stock, he "can and will continue to be able to effectively control," *inter alia*: (i) the election of Board members; and (ii) Insys's "management and [] affairs." Further, in the Company's Annual Report on Form 10-K for the 2015 fiscal year, filed with the SEC on February 29, 2016 ("2015 Annual Report"), Insys stated:

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific, medical and other personnel. ***We are highly dependent on our management***, scientific and medical personnel, as well as our board members, ***including our founder, President, Chief Executive Officer and principal stockholder, Dr. John N. Kapoor.***<sup>2</sup>

18. Kapoor therefore participated in the management and day-to-day operations of the Company and had actual knowledge of confidential proprietary information concerning Insys and its business, operations, growth, financial statements, and financial condition. Because of his position of control and authority, his ability to exercise power and influence with respect to Insys's course of conduct, and his access to material inside information about Insys during the Class Period, at all relevant times, Defendant Kapoor was a controlling person of Insys within the meaning of § 20(a) of the Exchange Act. As alleged herein, during the Class Period, Kapoor made materially false and misleading statements concerning the Company's finances, operational and compliance policies.

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<sup>2</sup> All emphasis added unless otherwise indicated.

19. On September 21, 2016, Insys announced that the Company’s Board had initiated a search to identify a new CEO to replace Kapoor as President and CEO, but assured investors that “Dr. Kapoor will continue to serve as President and CEO until his replacement is appointed.” Shortly thereafter, however, on January 9, 2017, Insys announced that Kapoor had abruptly retired, effective the same date, before the Board had identified a replacement CEO. The sudden retirement of Kapoor came amid growing public and regulatory scrutiny concerning an illicit kickback scheme at Insys to promote Subsys by paying doctors illegal remunerations. As a result of this scrutiny, numerous Insys employees, including Babich, Burlakoff, had been or would soon be arrested and indicted. Kapoor remains a member of Insys’s board of directors.

20. On October 24, 2017, Kapoor was indicted for racketeering conspiracy, mail fraud conspiracy, wire fraud conspiracy, and conspiracy for his role in the kickback scheme at Insys. *See Mass. Indictment.* On October 26, 2017, he was arrested on these charges.

21. Individual Defendant Santosh J. Vetticaden was the Interim CEO of Insys from January 9, 2017 until April 28, 2017, and was also the Chief Medical Officer (“CMO”) of Insys from January 2016 until April 28, 2017. Vetticaden was appointed Interim CEO following Kapoor’s sudden retirement. Insys emphasized the critical importance of Vetticaden as Interim CEO and Chief Medical Officer in SEC filings and press releases filed or issued throughout the Class Period. For instance, in the Company’s January 9, 2017 Press Release announcing his appointment as Interim CEO, Insys emphasized Vetticaden’s experience and “passion for drug development and commercialization for over 20 years in diverse areas.” Vetticaden received his Ph.D. from the Virginia Commonwealth University, his M.D. from the University of Maryland, and his M.B.A. from the Sloan School of Management at the Massachusetts Institute of Technology.

22. Vetticaden participated in the management and day-to-day operations of the Company and had actual knowledge of confidential proprietary information concerning Insys and its business, operations, growth, financial statements, and financial condition. Because of his position of control and authority, his ability to exercise power and influence with respect to Insys's course of conduct, and his access to material inside information about Insys during the Class Period, at all relevant times, Vetticaden was a controlling person of Insys within the meaning of § 20(a) of the Exchange Act. As alleged herein, during the Class Period, Vetticaden made materially false and misleading statements concerning the Company's finances, operational and compliance policies.

23. On March 31, 2017, Insys announced that the Audit Committee had concluded, upon the recommendation of Insys management, that the Company's previously issued financial statements as of and for the quarters ended September 30, June 30, and March 31, 2016 and 2015, should no longer be relied upon, and those financial statements would be restated. Only *seven business days later*, on April 11, 2017, Insys "accepted" the resignation of Defendant Vetticaden as both Interim CEO and Chief Medical Officer and stated his employment in both positions would be "terminated" effective April 28, 2017. In addition to the restatements, one week prior to Vetticaden's purported resignation, Insys reported disappointing fourth quarter and year-end 2016 results including a 41.5 percent decrease in net revenue for the quarter.

24. Individual Defendant Darryl S. Baker was the Chief Financial Officer ("CFO") of Insys from October 2012 until July 18, 2017. According to the Company's Schedule 14A Proxy Statement filed with the SEC on April 20, 2016, Baker was hired due to his "extensive experience in accounting [and] SEC compliance." Baker himself purports to be well versed in SEC compliance, as his LinkedIn profile touts his "specialties" as, among other things, "Investor

relations, entrepreneurial business operations and finance...SEC reporting for non-accelerated filers, [and] Sarbanes-Oxley compliance.” Baker also has more than twenty years of accounting experience at publicly traded companies and holds a B.S. in Accountancy from the Marriott School of Management at Brigham Young University. Prior to his employment with Insys, from February 2009 until May 2012, Baker was the Chief Financial Officer, Vice President, and Treasurer of iGo, Inc. after previously serving as iGo, Inc.’s Chief Accounting Officer from April 3, 2006 to May 21, 2012 and its Controller from October 2001 to 2012.

25. Baker directly participated in the management and day-to-day operations of the Company and had actual knowledge of confidential proprietary information concerning Insys and its business, operations, growth, financial statements, and financial condition. Moreover, because of his position of control and authority, his ability to exercise power and influence with respect to Insys’s course of conduct, and his access to material inside information about Insys during the Class Period, at all material times, Baker was a controlling person of Insys within the meaning of § 20(a) of the Exchange Act. As alleged herein, during the Class Period, Baker made materially false and misleading statements concerning the Company’s finances, operational and compliance policies.

26. On May 16, 2017, roughly a month and a half after Insys’s March 31, 2017 announcement that the Company’s previously issued interim unaudited condensed consolidated financial statements as of and for the quarters ended September 30, June 30, and March 31, 2016 and 2015 should no longer be relied upon and would be restated, Insys announced that Baker would “transition” out of the role of CFO when a successor was hired. To that end, Insys also disclosed that it had engaged an executive search firm to identify a new CFO. On July 18, 2017,

Insys announced that the Company had hired Andrew G. Long as CFO, and Baker's employment was accordingly terminated shortly thereafter.

27. Kapoor, Vetticaden, Babich, and Baker are collectively referred to herein as the "Individual Defendants." Insys and the Individual Defendants are collectively referred to herein as the "Defendants."

### **STATEMENT OF FACTS**

#### **I. Company Background**

##### **A. Insys's Success Is Dependent on the Sale of Subsys, Its Only Product on the Market.**

28. Insys is a commercial-stage specialty pharmaceutical company that develops and commercializes supportive care products primarily designed to assist patients with pain management attributable to their disease, treatments, or therapies. Since its inception as a publicly traded Company in May 2013, and throughout the Class Period, Insys's principal product and virtually exclusive source of revenue has been the prescription medication Subsys, a sublingual fentanyl spray designed to treat breakthrough cancer pain, or BTCP,<sup>3</sup> in opioid tolerant patients by delivering fentanyl for transmucosal absorption underneath the tongue.

29. As a Transmucosal Immediate Release Fentanyl ("TIRF") medication, Subsys is subject to the TIRF Risk Evaluation and Mitigation Strategy ("REMS") Access program pursuant to which all prescriptions of Subsys are tracked and reported in real-time. The purpose of the TIRF-REMS Access Program is to mitigate the risks of misuse, abuse, addiction, overdose, and serious complications due to medication errors with the use of TIRF medicines. As such, the TIRF-REMS Access Program keeps an updated list of all patients enrolled in the program, and keeps track of

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<sup>3</sup> BTCP is pain that comes on suddenly and is not alleviated by a cancer patient's normal pain-management plan.

actual prescription data for the TIRF medicines in the program in real time, enabling Defendants to precisely monitor sales of Subsys in real-time.

30. Prescribers of TIRF medicines, including Subsys, are required to enroll in the TIRF REMS Access Program.

31. Pharmacies and distributors of TIRF medicines, including Subsys, are also required to enroll in the TIRF REMS Access Program.

32. By November 2013 – less than two years after its launch – Subsys had become the most-prescribed branded TIRF medication, accounting for nearly one third of the market. According to Insys's 2016 Annual Report, as of December 2016, Subsys was “the most prescribed TIRF product, with 42% market share on a prescription basis,” making it the fastest growing TIRF product by market share:

	<b>Percentage Subsys Revenue Growth (As Reported)</b>	<b>Percentage TIRF Market Share</b>
FY2012	\$15.5 million	Subsys Launched
FY2013	\$99.3 million (+ 542%)	16.1%
FY2014	\$219.5 million (+ 124%)	40.2%
FY2015	\$330.3 million (+ 49%)	46.8%
FY2016	\$242.3 million (- 26.7%)	42.0%

33. Moreover, as reflected in the chart below, since becoming a publicly traded Company, prescriptions of Subsys have accounted for more than 98 percent of Insys's net revenues:

	<b>Subsys Net Revenue (in millions)</b>	<b>Total Net Revenue (in millions)</b>	<b>Percent of Total Net Revenue</b>
FY2014	\$219.5	\$222.1	98.83%
1Q2015	\$70.5	\$70.8	99.60%
2Q2015	\$76.7	\$77.6	98.84%
3Q2015	\$91.3	\$91.26	99.78%
4Q2015	\$91.1	\$91.1	100%
FY2015	\$330.3	\$330.3	100%
1Q2016	\$62.0	\$62.0	100%

	<b>Subsys Net Revenue (in millions)</b>	<b>Total Net Revenue (in millions)</b>	<b>Percent of Total Net Revenue</b>
2Q2016	\$67.1	\$67.1	100%
3Q2016	\$55.2	\$55.2	100%
4Q2016	\$54.9	\$54.9	100%
FY2016	\$242.3	\$242.3	100%

34. Throughout the Class Period, Defendants repeatedly acknowledged that “[Insys is] largely dependent on the commercial success of our product, SUBSYS®...[w]e anticipate that in the near term our ability to maintain profitability will depend upon the continued commercial success of our main approved product, SUBSYS®.” Thus, by Defendants’ own admission, the continued volume sales of Subsys were critical to Insys’s long-term viability, a highly material aspect of Insys’s business operations, and its “lead” product or “core” business.

**B. The Majority of Insys’s Revenue From Subsys Is Derived From Reimbursements Received From Third-Party Payers.**

35. Prior to and throughout the Class Period, the overwhelming majority of Subsys revenues were from “third-party payers’ [] reimbursement [of] all or part of the costs.” *See* 2016 Annual Report.

36. Defendants repeatedly acknowledged the “critical” nature of Insys’s reimbursement relationships with third-party payers, stating, *inter alia*:

- “Our sales of, and revenue from, Subsys depended in significant part on the coverage and reimbursement policies of third-party payers, including government payers such as Medicare and Medicaid, and private health insurers.” *See* 2016 Annual Report.
- “If Subsys . . . do[es] not maintain broad market acceptance or coverage by third-party payers, the revenues that we generate from this product will be limited.” *Id.*
- “The commercial success of our products and our ability to commercialize any approved product candidates successfully will depend in part on the extent to which governmental authorities, private health insurers and other third-party payers provide coverage for and establish adequate reimbursement levels for our products, product candidates, and related treatments.” *Id.*

- “[O]ur ability to continue to generate revenues from this product will depend on a number of factors, including, but not limited to: achievement of broad market acceptance and coverage by third-party payers for our products; [and] the effectiveness of our efforts in marketing and selling SUBSYS®.” *Id.*
- “Our ability to generate revenue is affected by the availability of third-party reimbursement for SUBSYS® and our results of operations will be negatively affected if we fail to manage adequate reimbursement levels for SUBSYS® from such third-party payers.” *Id.*
- “Our sales of, and revenue from, SUBSYS® (and our anticipated future revenue from SYNDROS™) depend in significant part on the coverage and reimbursement policies of third-party payers, including government payers such as Medicare and Medicaid, and private health insurers.” *Id.*

37. Defendants made nearly identical statements in the Company’s periodic SEC filings throughout the Class Period. Thus, by Defendants’ own admission, Insys’s reimbursement relationships with government payers related to Subsys was critical to the Company’s sustained revenue growth and long-term viability.

38. The reimbursement for Subsys by third-party payers is highly regulated. In particular, due to its significant potency and high potential for abuse, fentanyl – which is the active pharmaceutical ingredient in Subsys – is categorized by the DEA as a Schedule II substance under the Controlled Substances Act and its manufacture, sale, marketing, and reimbursement by third-party payers is therefore constrained. Indeed, the FDA expressly states that Subsys is not indicated for a variety of “off-label” uses, including for the management of acute pain such as neck or back pain, or migraines.

39. Not only can Subsys be dangerous or deadly when used outside its label’s narrow indication, but it is also extremely expensive, at a cost that ranges from \$3,500 to \$40,000 per 30-

day supply.<sup>4</sup> As explained in the 2016 Annual Report, both private and public health insurance providers do not automatically cover every single drug that may be prescribed to an insured, but instead, they limit payments for drugs to those prescribed for “on-label” uses (i.e., for Subsys, for the treatment of BTCP in opioid tolerant cancer patients), and also establish levels of reimbursement for prescriptions in accordance with their growing emphasis on pharmaceutical price control. Thus, in general, to receive reimbursement by third-party payers, Subsys must: (i) only be prescribed for its approved use to manage BTCP in adults; and (ii) be priced at a rate that reflects third-party payers’ policy of price control.

40. To offset the cost of prescription drugs to commercial health insurance plans and government payers, Insys participates in various rebate programs, pursuant to which the Company provides discounted prescriptions to qualified insured patients. Under these rebate programs, Insys pays a rebate to the third-party administrator of the program, generally two to three months after the quarter in which prescriptions subject to the rebate are filled.

41. According to the 2016 Annual Report, Insys accrues rebates at the time revenue is recognized “based on current contract prices, historical and estimated future percentages of product sold to qualified patients and estimated levels of inventory in the distribution channel.” The allowance for rebates is included in the Company’s accrued sales allowances and operates to reduce reported net revenue.

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<sup>4</sup> See, e.g., First Script, “Drug Trends Analysis,” July 2016 at 25, available at <[https://coventrywcs.com/content/dam/pdf\\_assets/drug\\_trends/2015-DrugTrendsAnalysis.pdf](https://coventrywcs.com/content/dam/pdf_assets/drug_trends/2015-DrugTrendsAnalysis.pdf)>; see also Kansas Insurance Department, “Pharmaceutical Cost Report: Pharmaceutical Cost Trends 2014 & 2015,” available at <<http://www.ksinsurance.org/documents/healthlife/health/Pharmaceutical-Cost-Trends.pdf>>.

**C. Insys Closely Monitored Authorization and Reimbursement Rates Through Its Insurance Reimbursement Center.**

42. As a mandated participant in the TIRF-REMS Access Program, Insys received quarterly reports on the prescription and usage of TIRF medicines and had daily access to the number of Subsys prescriptions being written in real time. For example, according to the 2016 Annual Report, Insys monitors the rate of Subsys subscriptions in any given quarter using real-time data from the TIRF-REMS Access Program and receives “[m]onthly prescription data” reports. At a December 1, 2015, Piper Jaffray healthcare conference, Defendant Kapoor elaborated on the Company’s access to, and policy and practices related to monitoring the number of Subsys prescriptions in real-time, stating:

The factual information is that the Subsys market, when we entered, had about roughly 10,000 scripts a month, and today roughly the same. And we started with zero and today we have almost 50% market share. And *if you analyze this, which we do every day, we have a meeting every day at 8:30 in the morning looking at what happened yesterday. I can tell you how many scripts we did yesterday. And we do that every single day, because Subsys is so important to us.*

43. The Company’s management also established the Insys Insurance Reimbursement Center (“IRC”) in 2012 to interact with third-party payers to obtain prior authorization and insurance coverage for expensive Subsys prescriptions. The Company’s IRC worked extensively with third-party payers to evaluate price increases and secure insurance coverage for Subsys on behalf of patients. For instance, Insys has touted its relationships and communications with third-party payers, stating:

- “[W]e remain in contact with all the insurance plans and PBMs . . . [W]e continue to properly communicate with all the major plans and the PBMs to ensure proper access for Subsys.” *See August 12, 2014 Earnings Call Transcript.*
- “We provide administrative reimbursement support assistance, in large part through our insurance reimbursement support hub, which provides administrative support assistance to help patients coordinate with their insurance companies.” *See Form 10-Q for the Second Quarter 2015, filed on August 6, 2015.*

- “We’re hopeful and optimistic that as we continue to engage in dialogue with payers, as we continue to educate them on the benefits of these medications, that that pressure will start to subside and loosen and we will be able to see both improvements in gross to nets and improvements in script volumes as we move forward.” *See February 23, 2017 Earnings Call Transcript.*
- “I think our strategy will be to continue to price in the range with the class, and continue to dialogue with payers on why they should be reimbursing TIRF products.” *Id.*

44. Accordingly, Insys was able to, and did, monitor the number of Subsys prescriptions written on a daily basis, in real time; actively reviewed and discussed the Subsys prescription data on a daily basis and knew exactly how many Subsys prescriptions were written and filled on any given day. Defendants thus knew before the beginning of the Class Period that third-party payers were refusing to reimburse off-label Subsys prescriptions as they became aware that the Company had fraudulently secured from doctors through the widespread kickback scheme described below; consequently, sales were declining and distributors were returning Subsys orders in accordance with the Company’s return policy.

**D. Insys Top Management Admittedly Monitors the Company’s Main Customers’ Inventory Levels Through Inventory Reports Received Directly From Customers.**

45. Insys does not sell Subsys directly to patients. Rather, the majority of Insys’s sales of Subsys “are to wholesale pharmaceutical distributors who, in turn, sell the products to pharmacies, hospitals, and other customers.” *See 2016 Form 10-K.* The remainder are to specialty pharmaceutical retailers.

46. For the year ended December 31, 2016, Insys’s four largest wholesale pharmaceutical distributor customers were Rochester Drug Cooperative, Inc. Amerisource Bergen Corporation, McKesson Corporation, and Cardinal Health, Inc., accounting for 15 percent, 17 percent, 16 percent, and 14 percent, respectively, of Insys’s total Subsys product shipments. *See*

*id.* Together those sales accounted for 67 percent of Insys's gross revenue for the year ended December 31, 2016, and 83 percent of gross revenues for the year ended December 31, 2015. According to the 2016 Form 10-K, top management, “[p]ursuant to distribution service agreements with [Insys's] three largest wholesale customers, [] receive[d] inventory level reports” during the Class Period. *See id.*

47. Direct sales of Subsys to a single specialty pharmaceutical retailer accounted for 32 percent of Insys's total shipments and 33 percent of gross revenue for the year ended December 31, 2016; sales to specialty pharmaceutical retailers accounted for 5 percent of gross revenues for the year ended December 31, 2015.

**II. Third-Party Payers Cease Approving and/or Reimbursing for Off-Label Prescriptions of Subsys Upon Revelation of the Company's Illegal Kickback Scheme.**

48. Kickback-tainted claims are non-reimbursable by government health insurers because compliance with the federal anti-kickback statute (42 U.S.C. § 1320a-7b(b)) is a condition of payment of any claims submitted for payment to government-run healthcare programs. These programs include Medicare, the state Medicaid programs, TRICARE (formerly the Civilian Health and Medical Program of the Uniformed Services), the Civilian Health and Medical Program of the Department of Veteran's Affairs, the Federal Employees Health Benefits Plan and other federal health care programs. Providers of pharmaceuticals for patients of government-run health care programs, including pharmaceutical manufacturers like Insys, typically certify that they will comply with all applicable federal and state laws and acknowledge that they will be subject to criminal or civil penalties for any violations. In many cases, the providers also expressly

acknowledge that fraudulent or falsified claims will not be reimbursed and will be subject to recoupment.<sup>5</sup>

49. Similarly, private health insurers may be able to recoup payments under a variety of state laws for non-reimbursable prescriptions when a pharmaceutical company engaged in fraudulent or deceptive activity to obtain authorization for those prescriptions.<sup>6</sup>

50. Despite their knowledge that tainted claims would not be reimbursed or would be subject to recoupment, and since Insys's inception as a publicly traded Company, Defendants perpetuated a fraud, at the direction of management, in which Insys: (1) engaged in an illegal kickback scheme to induce third-party payers to prescribe Subsys for off-label use; and (2) provided economic incentives and encouragement, as well as intense pressure, to sales representatives and managers to promote Subsys for off-label uses.

51. The aggressive tactics employed by Insys were refined by Individual Defendants over the course of decades. For example, in 1992, Kapoor co-founded a company called First Horizon Pharmaceutical Corp, which changed its name to Sciele Pharma, Inc. ("Sciele"), in 2006. Sciele which sold cardiac, pediatric, and allergy medications. Director Patrick Fourteau eventually joined Kapoor at Sciele and the two developed a scheme of hiring recent college graduate, nurses, and other health-care professionals, rather than experienced pharmaceutical salespeople. According to Fourteau, Fourteau and Kapoor's strategy was to paid sales representatives low salaries, but offer large bonuses if they were able to get doctors to prescribe

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<sup>5</sup> See, e.g., Texas State Medicaid Provider Enrollment Application at § 5.2, available at <[http://www.tmhp.com/provider\\_forms/provider%20enrollment/texas%20medicaid%20provider%20enrollment%20application.pdf](http://www.tmhp.com/provider_forms/provider%20enrollment/texas%20medicaid%20provider%20enrollment%20application.pdf)>.

<sup>6</sup> See, e.g., *Blue Cross of California Inc., et al. v. Insys Therapeutics Inc.*, No. 2:17-cv-02286 (D. Ariz.).

Sciele's drugs. Fourteau would join Insys's Board of Directors in 2011, where Insys, with Fourteau's active guidance, replicated Sciele's incentive-based sales strategy.

52. The kickback scheme began to unravel beginning in September 2014 when Insys received a subpoena from the U.S. Attorney's office for the District of Massachusetts, and ultimately culminated in the arrest and indictment of Defendant Babich and former Vice President of Sales Burlakoff in December 2016 for operating a nationwide criminal enterprise under the Racketeer Influenced Criminal Organizations Act ("RICO").<sup>7</sup> This fraudulent kickback scheme was described by the Oregon Assistant Attorney General in November 2015 as "the most unconscionable that I've seen."<sup>8</sup> Investigations into Insys's criminal activity are ongoing.

53. According to an article by the Southern Investigative Reporting Foundation ("SIRF"),<sup>9</sup> third-party payers were frequently calling the office of the prescribing physician in order to confirm every aspect of the diagnosis to ensure that the prescription was for an on-label indication.

54. In addition, it was standard practice at Insys during the Class Period for IRC employees to proactively contact PBMs themselves using a misleading "spiel" developed by high-level Insys employees. For example, in a January 2015 telephone call,<sup>10</sup> an Insys IRC

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<sup>7</sup> *USA v. Babich et al.*, No. 1:16-cr-10343-ADB, Dkt. 1 (filed Dec. 6, 2016).

<sup>8</sup> Gusovsky, Dina, *The Pain Killer: A Drug Company Putting Profits Above Patients*, CNBC at <http://www.cnbc.com/2015/11/04/the-deadly-drug-appeal-of-insys-pharmaceuticals.html?view=story&%24DEVICE%24=native-android-tablet> (accessed Jul. 22, 2017).

<sup>9</sup> Roddy Boyd, *The Brotherhood of Thieves: Insys Therapeutics*, SOUTHERN INVESTIGATIVE REPORTING FOUNDATION at <http://sirf-online.org/2016/01/25/the-brotherhood-of-thieves-insys-therapeutics-2/> (accessed Jul. 24, 2017).

<sup>10</sup> See U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office, *Fueling an Epidemic: Insys Therapeutics and the Systemic Manipulation of Prior*

representative falsely stated to an employee of a PBM that she was “with the doctor’s office.” The representative then allowed the PBM to believe that the prescription was for the treatment of breakthrough cancer pain:

PBM: Hello, Gina? Hi, Gina, thanks for holding, I appreciate your patience. So is this initial or continuing therapy?

Insys rep: This is initial.

PBM: OK, and what is the diagnosis for the patient?

Insys rep: Uh, let me look here . . . [inaudible] . . . medication is intended for the management of breakthrough cancer pain. The doctor is treating the patient for breakthrough pain with a diagnosis code of 338.29 [chronic pain]—

[. . .]

PBM: Thank you. [pause] Is it also for the breakthrough cancer pain or not?

Insys rep: Well, there’s no code for breakthrough cancer pain.

PBM: Yeah, and that’s fine. I typed out the description. I just wanted to make sure that I heard you correctly.

Insys rep: It’s for breakthrough pain, yeah.

PBM: Good. Ok.

55. The patient referred to above did not have breakthrough cancer pain. Nor did she even have cancer. She died three months later “due to an adverse reaction to prescription medication.” During the 14-month period in which she received Subsys treatment, Medicare paid as much as \$24,000 per month for her prescriptions.<sup>11</sup> Such improper sales led to increased

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*Authorization, Minority Staff Report, Sept. 1, 2017; audio recording available at <https://qz.com/1074509/a-drug-company-schemed-to-push-opioids-designed-to-treat-cancer-on-cancer-free-patients/>.*

<sup>11</sup> See Complaint, *Fuller v. Matalan et al.*, No. L1859-17 (Middlesex Cnty., NJ Sup. Ct. Mar. 23, 2017).

purchases of Subsys by wholesalers and pharmacies, and greater revenue for Insys, which Insys improperly recorded as revenue.

56. According to a former IRC employee interviewed by *SIRF*, and identified in a January 2016 article as cooperating with the ongoing federal investigation, by 2015, third-party payers became aware of the fact that the IRC was using scripted responses to falsely imply that the patient at issue had been diagnosed with BTCP.

57. Indeed, in June 2017, the former manager of the IRC, Elizabeth Gurrieri, pleaded guilty to wire fraud conspiracy in Massachusetts federal court in connection with the practice of misleading health insurers.<sup>12</sup>

58. As a result of the increased scrutiny resulting from the government investigations, beginning in 2015, third-party payers increasingly denied Insys's coverage requests. Some third-party payers categorically removed Subsys from any coverage. For example, PBM Express Scripts announced in August 2015 that it would exclude Subsys from its list of covered drugs in 2015 (2015 Form 10-K), and UnitedHealth Group, which owns the PBM OptumRX, did the same in 2016 (2016 Form 10-K).

59. Other third-party payers have taken the affirmative step of seeking reimbursement from Insys for making false statements to obtain authorization. A group of health insurers has alleged that since 2013, "Insys's schemes . . . [have driven] significant off-label use and secur[ed] payments in excess of \$19 million from Anthem for Subsys® prescriptions that were not covered, in addition to the millions of dollars in cost-sharing obligations imposed on Anthem members."<sup>13</sup>

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<sup>12</sup> *United States et al. ex rel. Furchak v. Insys Therapeutics, Inc. et al.*, No. 4:12-vb-02930, (S.D. Tex.).

<sup>13</sup> See *Blue Cross of California Inc., et al. v. Insys Therapeutics Inc.*, No. 2:17-cv-02286 (D. Ariz.).

60. Defendants have acknowledged that Insys was receiving “significant pressures” from third-party payers with respect to reimbursements, stating on a November 30, 2016 analyst call for example: “[o]ne of the significant pressures for us is from – on the part of third-party payers, who have made it more difficult for patients to secure reimbursement for their scripts.” For example, Insys disclosed in its 2015 Form 10-K that Humana, a provider of Medicare Part D prescription drug insurance, was seeking to recoup from pharmacies approximately \$5.6 million in improper off-label claims for Subsys prescriptions.

61. In the face of this pressure and increasing reluctance of third-party payers to provide reimbursement for Subsys, Insys could no longer maintain its streak of reporting consistently increasing quarterly Subsys net revenues and profits. Moreover, Insys was forced to offer increased discounts and rebates to third-party payers and patients, and, as Insys was unable to secure filled prescriptions for Subsys, distributors and pharmacies began returning product.

62. In order to compensate for the decline in revenue growth, Defendants admittedly embraced an admitted “tone at the top” where, *in violation of the Company’s own internal accounting policies*, Insys prematurely recorded revenue and failed to properly account for sales allowances, thereby overstating revenue and earnings.

### **III. Defendants Institute a “Tone at the Top” to Engage in Accounting Manipulations in Order to Conceal the Company’s Declining Subsys Revenues.**

#### **A. Defendants Prematurely Recognize Revenue for Subsys Before It Was Sold to the End-User or the Right of Return Expired.**

63. According to Insys’s SEC filings, the Company’s stated revenue recognition policy requires Insys to recognize revenue from the sale of Subsys when “(i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured.” In violation of Insys’s stated policies,

however, the Company recognized revenue on sales of Subsys when it was sold to the distributor, rather than when the drug was sold to the actual end-user or the right of return had expired.

64. During the Class Period, Defendants knowingly participated in and approved of sales and marketing practices that endangered Insys's ability to receive third-party payer reimbursement and future fulfilled prescriptions. In particular, they oversaw and approved of the IRC's strategy of misrepresenting patients' medical conditions; gave sales representatives and IRC employees financial incentives to secure doctors' prescriptions and obtain illegal authorizations; and actively encouraged aggressive sales practices, including a vast scheme of blatantly illegal kickbacks. As set forth above, one result of the revelation of this misconduct was that third-party payers increasingly refused to reimburse for improper Subsys prescriptions.

65. The concomitant negative business consequences associated with these practices materialized over the Class Period: while approximately 43,000 Subsys prescriptions were written in 2015, only about 31,000 were written in 2016, a drop of over 25 percent.<sup>14</sup> At the same time that Defendants saw (through their daily review of prescription numbers) that prescription numbers were dropping, Insys also had access to direct reports concerning inventory levels at the three customers accounting for nearly half of its shipments. Moreover, by 2016, 94 percent of Insys's Subsys shipments were made to only five companies (four wholesalers and one retail pharmacy). Defendants therefore would have known that the rate at which prescriptions were being filled would not keep pace with the large volume of inventory in the Subsys distribution channels. Having anticipated lower rates of fulfilled prescriptions, Defendants should not have recognized

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<sup>14</sup> Forty-six percent of TIRF prescriptions written in 2015 and 43 percent of TIRF prescriptions written in 2016. *See Form 10-K at 63.*

revenue associated with shipments of Subsys that would be subject to revenue-reducing rebates and discounts or would be returned to them.

66. Insys's practice of recognizing revenue when the drug was sold to distributors resulted in revenue being overstated during the Class Period in violation of GAAP and Insys's own internal accounting policies because the Company recognized revenue before the price was fixed or determinable as a result of the distributor's lengthy right of return and rebates and discounts payable to third-party payers and patients. In fact, as Defendants would ultimately admit, the Company's premature recognition of revenue was the direct result of an inadequate "*tone at the top*" amongst management, who enabled the Company to perpetuate an illusion of continued financial health in the face of continued pressure by third-party payers.

67. Defendants' aggressive and manipulative accounting practices would eventually catch up to the Company, just like its illegal kickback scheme, forcing Insys to restate years' worth of revenue, which Defendants admit was "material" to Insys's financial results.

**B. Defendants Fail to Properly Recognize Product Returns and Rebates, Which Could Not Be Reasonably Estimated Based on Insys's Lengthy Return Policy.**

68. Distributors were allowed to return Subsys for a full refund "within six months before and up to 12 months following its product expiration date." The shelf life of Subsys is 36 months from the date of manufacture. Thus, distributors had up to four years to return Subsys after the date of its manufacture and could return Subsys even after the product had expired. The Company's product return policy and GAAP required Defendants to record estimated product returns as an increase to the Company's allowance and a reduction of revenue in the same period the related revenue was recognized.

69. Insys also offered rebates to third-party payers generally two to three months after the quarter in which the prescription was filled. According to Insys's internal policy, the Company

records estimated rebates in accrued sales allowances “as a reduction of revenue *in the period the related revenue is recognized.*” Beginning by at least 2015, however, when Insys’s illegal kickback scheme came to light, third-party payers were refusing to reimburse for Subsys and distributors were also returning significantly more Subsys product. In fact, *between year-end 2014 and year-end 2016, the cost of the Company’s returns increased 120 percent from \$1,159,000 to \$2,552,000*, according to the 2016 Annual Report.

70. In accordance with Insys’s own stated internal policies, as distributors began returning unused, expired Subsys orders, Defendants were required to increase the Company’s sales allowance. Yet in order to conceal increased returns, as part of the same admitted “*tone at the top,*” Defendants failed to properly record Insys’s product sales allowances at the time revenue was recognized.

71. Indeed, as demonstrated in the chart below, even as the turmoil within Insys increasingly became public, the percentage of accrued sales allowance remained constant:

(in thousands unless otherwise stated)	<b>As Restated</b>			
	<b>2016</b>	<b>2015</b>	<b>2014</b>	<b>2013</b>
Net Revenue	\$242,275	\$330,323	\$219,062	\$99,289
Provision for Discounts, Rebates & Returns	\$137,000	\$126,600	\$63,700	\$19,100
Gross Revenue	\$379,275	\$456,923	\$282,792	\$118,389
Accrued Sales Allowance	\$28,955	\$35,033	\$14,329	\$5,340
% of Accrued Sales Allowance/ Revenue	7.6%	7.7%	5.1%	4.5%

72. Further, while Defendants represented that Insys “monitored actual return history since [the Subsys] launch,” contrary to these public statements, the Company was did not reasonably estimate returns. Subsys had only been on the market since 2012 and while Insys represented that it had an adequate return history upon which to base its allowance for returns, the

Company's return policy was very long. Accordingly, Defendants admittedly knew actual rates of product returns, real-time, but chose not to alter the product sales allowance.

**IV. The Audit Committee of the Insys Board of Directors Commences an Internal Investigation of the Accounting Fraud.**

73. Insys's scheme to inflate its revenue and to distort the truth about its profitability could not continue forever. Rather, the scheme imploded when, on March 15, 2017, Insys issued a press release announcing a delay in providing its fourth quarter and full year 2016 financial results. The March 15 Press Release disclosed that the Audit Committee of the Board of Directors (the "Board") had "been conducting" an independent review of the Company's processes related to "estimation of, and increases to, certain sales allowances recorded during 2016, with a potential reduction of 2015 net revenue and pre-tax income not expected to exceed \$5 million, as well as extended payment terms offered to certain customers during the third quarter of 2016." The same day, Insys filed a notification of late filing on Form 12b-25 with the SEC to obtain an automatic 15-day extension of the filing deadline for its 2016 Annual Report.

74. The Audit Committee reached these determinations after engaging independent legal counsel and a forensic accounting firm to assist its investigation related to the Company's estimation of, and increases to, certain net revenue adjustments, as well as related process issues and extended payment terms offered to certain customers. This investigation resulted in a restatement of the Company's financial results for several years.

**POST-CLASS PERIOD EVENTS**

**I. Insys Announces "Material" Restatements to the Company's Interim Financial Statements Resulting from a "Tone at the Top" and Woeful Lack of Internal Controls.**

75. Two weeks after the ongoing Audit Committee Investigation was disclosed, on March 31, 2017, the Company announced that the Committee had concluded, upon the

recommendation of management, that the Insys's previously issued interim unaudited condensed consolidated financial statements as of and for the quarters ended September 30, June 30, and March 31, 2016 and 2015, should no longer be relied upon, and those financial statements would be restated due to the identification of certain errors. Insys expressly acknowledged, among other things, that *the impact of these errors was material*. Further, Insys later acknowledged that the restatements were the result of an inadequate "tone at the top" amongst management.

76. The specific false statements identified in the March 31 Press Release, according to Defendants, resulted from errors related to the Company's accounting for certain of its product sales allowances, including its rebate obligations and returns from government payer and managed care contracts. Defendants further announced that they would reverse an out-of-period adjustment related to a stock option modification previously recorded during the three months ended March 31, 2016 that related to the fourth quarter of 2015, and would also reverse an out of period adjustment of \$834,000 recorded during the three months ended December 31, 2016 that related to the deductible interest portion of an accrued litigation award recognized during the three months ended June 30, 2015.

## **II. The Chief Operating Officer, Chief Executive Officer, Interim Chief Executive Officer, Chief Medical Officer, and Chief Financial Officer of Insys "Resign" or Are "Terminated."**

77. As Defendants struggled to conceal the true extent of third-party payer pressure and distributor returns, and investors began to learn the truth regarding their fraudulent financial manipulations, the Company's Chief Operating Officer, Chief Executive Officer, Interim Chief Executive Officer, Chief Medical Officer, and Chief Financial Officer (*i.e.* the entire executive management team) resigned or were outright terminated over the course of only nine months. First, on August 10, 2016, only seven days after Insys announced a 13.1 percent decrease in total net

revenue for the second quarter 2016 to \$67.1 million, the Company announced that the employment of Dan Brennan (“Brennan”), the Executive Vice President and Chief Operating Officer of Insys, had been inexplicably “terminated.” Brennan had just recently joined Insys in November 2015 to rehabilitate its compliance department after Individual Defendant Babich was forced to step down amid the public revelation of the Company’s widespread kickback scheme. Thus, his abrupt termination came only nine months after his initial appointment.

78. Roughly one month after Brennan’s termination, on September 21, 2016, Insys announced that the Company’s Board had initiated a search to identify a new CEO to replace then-CEO Kapoor as President and CEO. Kapoor had assumed the positions only one year prior, following the resignation and subsequent arrest and criminal indictment of Defendant Babich, and former Vice President of Sales, Burlakoff. The September 2016 Press Release specifically assured investors that “Dr. Kapoor will continue to serve as President and CEO until his replacement is appointed,” yet inexplicably, on January 9, 2017, Insys announced that Defendant Kapoor had abruptly retired, effective the same date, before the Board had identified a replacement. Kapoor’s sudden retirement came amid growing public and regulatory scrutiny concerning the above detailed illicit kickback scheme at Insys to promote Subsys.

79. Kapoor was succeeded by Defendant Vetticaden, who was appointed Interim CEO on January 9, 2017. Only three months after initial his appointment, however, and only seven business days after the Company’s March 31, 2017 announcement that its previously issued financial statements should no longer be relied upon, Insys announced on April 11, 2017 that it had “accepted” the resignation of Vetticaden as both Interim CEO and Chief Medical Officer and stated his employment in both positions would be “terminated” effective April 28, 2017. In addition to the restatements, one week prior to Vetticaden’s purported resignation, Insys reported

disappointing fourth quarter and year-end 2016 results including a 41.5% percent decrease in net revenue for the quarter.

80. One month after Vetticaden's purported resignation, and roughly a month-and-a-half after Insys's March 31, 2017 announcement that the Company's previously issued financial statements should no longer be relied upon, Insys announced on May 16, 2017 that Defendant Baker would "transition" out of the role of CFO when a successor was hired. To that end, Insys also disclosed that it had engaged an executive search firm to identify a new CFO. Prior to his termination, Defendant Baker had been the CFO of Insys since October 2012 and according to the Company, had "extensive experience in accounting, SEC compliance for smaller public companies, merger and acquisition transactions, and small business financing." On July 18, 2017, it was announced Insys had hired Andrew G. Long as CFO, and Baker's employment was accordingly terminated.

#### **DEFENDANTS' MATERIALLY FALSE AND MISLEADING CLASS PERIOD STATEMENTS AND OMISSIONS**

##### **I. False and Misleading Statements in the May 7, 2015 Press Release and First Quarter Earnings Call**

81. On May 7, 2015, the first day of the Class Period, the Company issued a press release announcing its first quarter 2015 financial results for the three-month period ended March 31, 2015 reporting the following relevant first quarter "highlights":

- Total net revenue increased to \$70.8 million versus \$41.6 million for the first quarter of 2014;
- Revenues from Subsys® (fentanyl sublingual spray) were \$70.5 million, up 74% compared with first quarter 2014 sales of \$40.7 million;
- Net income of \$8.0 million, or \$0.23 per basic and \$0.21 per diluted share, compared to net income of \$7.7 million, or \$0.23 per basic and \$0.21 per diluted share, for the first quarter of 2014.

82. In the May 7 Press Release, Defendant Babich lauded the Company's "strong quarter, driven by our *twelfth consecutive quarter of Subsys sales growth.*" Also on May 7, 2015, the Company held an earnings call to discuss the recently announced first quarter 2015 financial results. Therein, Defendant Baker repeated the same false and misleading revenue and net income numbers for the first quarter 2015 as reported in the May 7 Press Release.

83. The above statements were materially false and misleading when made because: Defendants had admittedly: (i) overstated revenue for the first quarter 2015; (ii) understated rebate obligations to third-party payers, product returns by distributors, and Insys's overall provisions for sales allowance; (iii) overstated earnings; (iv) as a result of (i) - (iii), Insys violated its own stated internal accounting policies for recording revenue, sales returns, rebates, and overall sales allowance; and, thus, (v) the Company's business and prospects were worse than represented. Moreover, Defendants failed to disclose that sales of Subsys were, in fact declining as a result of third-party payers refusing to prescribe and/or reimburse for off-label Subsys prescriptions as a result of Defendants' illegal kickback scheme.

84. Throughout the Class Period, the above material misstatements served to maintain the Company's inflated stock price. Indeed, as a result of the above misstatements, Insys's stock price increased 8 percent from \$26.73 per share on May 6, 2015 to close at \$28.88 per share on May 11, 2015.

## **II. False and Misleading Statements in the 2015 First Quarter Form 10-Q**

85. On May 11, 2015, Insys filed its first quarter report on Form 10-Q for the period ended March 31, 2015 ("2015 First Quarter Report") with the SEC, which was signed and certified by Individual Defendants Baker and Babich. The 2015 First Quarter Report contained materially false and misleading statements relating to Insys: (A) compliance with Company accounting

policies; (B) financial statements and their compliance with GAAP; and (C) adequacy of internal controls and procedures.

**A. False and Misleading Statements Concerning Compliance with Accounting Policies and GAAP**

86. In the 2015 First Quarter Report, Defendants falsely represented that Insys recognized revenue when four criteria were satisfied:

We recognize revenue from the sale of Subsys and Dronabinol SG Capsule. Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured.

87. With respect to sales allowances, Defendants falsely claimed that Insys recorded a product sales allowance at the same time revenue was recognized:

We recognize estimated product sales allowances as a reduction of product sales *in the same period the related revenue is recognized*. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with customers and third-party payers and the levels of inventory within the distribution channels that may result in future discounts taken. In certain cases, such as patient assistance programs, we recognize the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, we may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment.

88. Defendants similarly misrepresented that Insys recorded product rebates at the time revenue was recognized.

*Rebates.* We participate in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, we pay a rebate to the third-party administrator of the program, generally two to three months after the quarter in which prescriptions subject to the rebate are filled. We estimate and accrue these rebates based on current contract prices, historical and estimated future percentages of products sold to qualified patients and estimated levels of inventory in the distribution channel. *Estimated rebates are recognized as a reduction of revenue in the period the related revenue is recognized.* The allowance for rebates is included in accrued sales allowances.

89. With respect to product returns, Defendants falsely represented that Insys has a reasonable basis with which to estimate returns and that it properly recorded discounts in the accrued sales allowances:

*Product Returns.* We allow customers to return product for credit within six months before and up to 12 months following its product expiration date. The shelf life of Subsys is currently 36 months from the date of manufacture. We have monitored actual return history since product launch, which *provides us with a basis to reasonably estimate future product returns*, taking into consideration the shelf life of product at the time of shipment, shipment and prescription trends, estimated distribution channel inventory levels, and consideration of the introduction of competitive products.

Because of the shelf life of our products and our return policy of issuing credits on returned product that is within six months before and up to 12 months after its product expiration date, there may be a significant period of time between when the product is shipped and when we issue credits on returned product. Accordingly, we may have to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustments. *The allowance for product returns is included in accrued sales allowances.*

90. The above statements were materially false and misleading when made because Insys: (i) improperly recorded revenue before it was earned; (ii) failed to reserve for product returns and rebates; (iii) lacked any reasonable basis for estimating its sales allowance; (iv) violated that Company's own internal accounting policies; and (v) lacked the appropriate processes and controls to properly track product returns and rebates.

**B. False and Misleading Statements Concerning Insys's Financial Statements and Compliance With GAAP**

91. In the 2015 First Quarter Report, the Company reported net revenue and net income for the first quarter 2015 of \$70.8 million and \$8 million, respectively.

92. Insys reported also reported provisions for wholesaler discounts, patient discounts, rebates, and returns of \$8.0 million, \$17.0 million, \$8.4 million and \$0.6 million, respectively, from the sale of Subsys for the three months ended March 31, 2015, compared to \$3.8 million,

\$4.1 million, \$3.7 million and \$0.1 million, respectively, from the sale of Subsys for the three months ended March 31, 2014.

93. According to the 2015 First Quarter Report, the increase in revenue provisions was “primarily attributable to increased sales and higher volumes of patient assistance.” Moreover, Insys management stated the Company “expect[s] net revenue from sales of Subsys to continue to increase during the remainder of 2015 due primarily to anticipated increases in the number of prescriptions fulfilled, combined with changes in prescription strength mix.”

94. Finally, the 2015 First Quarter Report also falsely represented that “[t]he accompanying condensed consolidated financial statements are unaudited and have been prepared in accordance with U.S. generally accepted accounting principles, pursuant to rules and regulations of the Securities and Exchange Commission (the “SEC”).”

95. The above statements were materially false and misleading when made because: Defendants had admittedly: (i) overstated revenue for the first quarter 2015; (ii) understated rebate obligations to third-party payers, product returns by distributors, and Insys’s overall provisions for sales allowance; (iii) overstated earnings; (iv) as a result of (i) - (iii), Insys’s financial statements were not in compliance with GAAP; and (v) Insys’s business and prospects were worse than represented. Moreover, Defendants failed to disclose that sales of Subsys were, in fact declining as a result of third-party payers refusing to reimburse for off-label Subsys prescriptions as a result of Defendants’ illegal kickback scheme.

**C. False and Misleading Statements Concerning Insys’s Internal Controls Over Financial Reporting**

96. The 2015 First Quarter Report also falsely represented that Insys maintained adequate controls over the Company’s financial reporting:

**ITEM 4. CONTROLS AND PROCEDURES**

### Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our President and Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of such date, ***our disclosure controls and procedures were effective.***

97. The 2015 First Quarter Report also included certifications signed by the Individual Defendants, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, which represented that Insys's financial statements did not contain material misstatements or omissions, and that the Company employed internal disclosure controls over financial reporting and related disclosures. In this regard, the 2015 First Quarter Report contained a certification signed by Defendant Babich, which stated:

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO RULES 13a-14(a) AND 15a-14(a)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

I, Michael L. Babich, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2015 of Insys Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information

relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 11, 2015  
/s/ Michael L. Babich  
Michael L. Babich  
President and Chief Executive Officer

98. The 2015 First Quarter Report contained a separate certification signed by Defendant Baker, which contained a verbatim reproduction of Babich's certification statement above.

99. Moreover, the 2015 First Quarter Report contained certifications pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002, signed by Individual Defendants Babich and Baker, which stated:

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Insys Therapeutics, Inc. (the "Company"), for the quarter ended March 31, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned, Michael L. Babich, principal executive officer of the Company, and Darryl S. Baker, principal financial officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to his knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

By:

/s/ Michael L. Babich

Michael L. Babich

President and Chief Executive Officer  
(Principal Executive Officer)

Dated May 8, 2015

By:

/s/ Darryl S. Baker

Darryl S. Baker

Chief Financial Officer  
(Principal Financial Officer)

Dated May 11, 2015

100. The above statements were materially false and misleading when made because: Defendants had admittedly: (i) overstated revenue for the first quarter 2015; (ii) understated rebate obligations to third-party payers, product returns by distributors, and Insys's overall provisions for sales allowance; (iii) as a result of (i) and (ii) Insys's internal controls over not effective but, rather, woefully inadequate.

101. Throughout the Class Period, the above material misstatements served to maintain the Company's inflated stock price. Indeed, as a result of the above misstatements, Insys's stock price increased 8 percent from \$26.73 per share on May 6, 2015 to close at \$28.88 per share on May 11, 2015.

### **III. False and Misleading Statements in the August 6, 2015 Press Release**

102. On August 6, 2015, the Company issued a press release announcing its second quarter 2015 financial results for the three-month and six-month period ended June 30, 2015. Touting Insys's "strong quarter, driven by our thirteenth consecutive quarter of Subsys sales growth," the Company reported the following quarter "highlights":

- Total net revenue increased to \$77.6 million versus \$55.7 million for the second quarter of 2014;
- Revenues from Subsys® (fentanyl sublingual spray) were \$76.7 million, up 40% compared with second quarter 2014 sales of \$54.6 million;
- Net income was \$7.3 million, or \$0.10 per basic and diluted share, compared to net income of \$9.5 million, or \$0.14 per basic and \$0.13 per diluted share, for the second quarter of 2014.

103. Insys also reported net revenue and net income for the six months ended June 30, 2015 of \$148.4 million and \$15.3 million, respectively.

104. The above statements were materially false and misleading when made because: Defendants had admittedly: (i) understated revenue; (ii) understated rebate obligations to third-party payers, product returns by distributors, and Insys's overall provisions for sales allowance; (iii) improperly recorded an out of period adjustment of \$834,000 recorded during the three months ended December 31, 2016 that relates to the deductible interest portion of an accrued litigation award recognized during the three months ended June 30, 2015, resulting in a \$834,000 increase in income tax expense for the three months ended December 31, 2016; (iv) as a result of (i) - (iii),

Insys violated its own stated internal accounting policies for recording revenue, sales returns, rebates, and overall sales allowance; and, thus, (vi) the Company's business and prospects were worse than represented. Moreover, Defendants failed to disclose that sales of Subsys were, in fact declining as a result of third-party payers refusing to prescribe and/ or reimburse for off-label Subsys prescriptions as a result of Defendants' illegal kickback scheme.

#### **IV. False and Misleading Statements in the 2015 Second Quarter Report and Earnings Call**

105. On August 6, 2015, Insys filed its quarterly report on Form 10-Q for the period ended June 30, 2015 ("2015 Second Quarter Report") with the SEC, which was signed and certified by Individual Defendants Baker and Babich. The 2015 Second Quarter Report contained materially false and misleading statements relating to Insys: (A) compliance with Company accounting policies; (B) financial statements and their compliance with GAAP; and (C) adequacy of internal controls and procedures.

##### **A. False and Misleading Statements Concerning Compliance with Accounting Policies and GAAP**

106. In the 2015 Second Quarter Report, Defendants falsely represented that Insys recognized revenue when four criteria were satisfied:

We recognize revenue from the sale of Subsys and Dronabinol SG Capsule. Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured.

107. With respect to sales allowances, Defendants falsely claimed that Insys recorded a product sales allowance at the same time revenue was recognized:

We recognize estimated product sales allowances as a reduction of product sales *in the same period the related revenue is recognized*. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with customers and third-party payers and the levels of inventory within the distribution channels that may result in future discounts taken. In certain cases, such as patient assistance programs, we

recognize the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, we may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment.

108. Defendants similarly misrepresented that Insys recorded product rebates at the time revenue was recognized:

*Rebates.* We participate in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, we pay a rebate to the third-party administrator of the program, generally two to three months after the quarter in which prescriptions subject to the rebate are filled. We estimate and accrue these rebates based on current contract prices, historical and estimated future percentages of products sold to qualified patients and estimated levels of inventory in the distribution channel. Estimated ***rebates are recognized as a reduction of revenue in the period the related revenue is recognized.*** The allowance for rebates is included in accrued sales allowances.

109. With respect to product returns, Defendants falsely represented that Insys has a reasonable basis with which to estimate returns:

*Product Returns.* We allow customers to return product for credit within six months before and up to 12 months following its product expiration date. The shelf life of Subsys is currently 36 months from the date of manufacture. We have monitored actual return history since product launch, which ***provides us with a basis to reasonably estimate future product returns,*** taking into consideration the shelf life of product at the time of shipment, shipment and prescription trends, estimated distribution channel inventory levels, and consideration of the introduction of competitive products.

Because of the shelf life of our products and our return policy of issuing credits on returned product that is within six months before and up to 12 months after its product expiration date, there may be a significant period of time between when the product is shipped and when we issue credits on returned product. Accordingly, we may have to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustments. ***The allowance for product returns is included in accrued sales allowances.”***

110. The above statements were materially false and misleading when made because Insys: (i) improperly recorded revenue before it was earned; (ii) failed to properly reserve for product returns and rebates; (iii) lacked any reasonable basis for estimating its sales allowance;

(iv) Insys violated that Company's own internal accounting policies; and (v) lacked the appropriate processes and controls to properly track product returns and rebates.

**B. False and Misleading Statements Concerning Insys's Financial Statements and Compliance With GAAP**

111. In the 2015 Second Quarter Report, the Company reported net revenue for the three and six-months ended June 30, 2015 of \$77.6 million and \$148.4 million, respectively. Insys also reported Net Income for the three and six-months ended June 30, 2015 of \$7.3 million and \$15.3 million, respectively.

112. Insys also reported provisions for wholesaler discounts, patient discounts, rebates and returns of \$10.0 million, \$14.4 million, \$16.8 million and \$0.6 million, respectively, from the sale of Subsys for the three months ended June 30, 2015. Also on August 6, 2015, the Company held an earnings call reporting the same materially false and misleading statements as the 2015 Second Quarter Report. Therein, Defendant Baker falsely represented with respect to the Company's financial performance, *inter alia*:

Total net revenue for second quarter of 2015 was \$77.6 million, which was an increase of 39% as compared with \$55.7 million for the second quarter of 2014. ***The key driver continues to be Subsys. . . . As Mike mentioned, this was our 10th straight quarter of profitability.*** GAAP net income for the second quarter of 2015 was \$7.3 million or \$0.10 per diluted share compared to net income of \$9.5 million or \$0.13 per diluted share for the second quarter of 2014.

113. Further, when asked by an analyst on the call "what's the discounting and rebating [for Subsys] was for the quarter?", Defendant Baker responded that "we're netting approximately two-thirds of our gross revenue. And our gross-to-net for Q2 were in line and consistent with that pattern."

114. The 2015 Second Quarter Report also falsely represented that "[t]he accompanying condensed consolidated financial statements are unaudited and have been prepared in accordance

with U.S. generally accepted accounting principles, pursuant to rules and regulations of the Securities and Exchange Commission (the “SEC”).”

115. The above statements were materially false and misleading when made because: Defendants had admittedly: (i) understated revenue for the first quarter 2015; (ii) understated rebate obligations to third-party payers, product returns by distributors, and Insys’s provisions for sales allowance; (iii) as a result of (i) - (ii), Insys’s financial statements were not in compliance with GAAP; and (iv) Insys’s business and prospects were worse than represented. Moreover, Defendants failed to disclose that sales of Subsys were, in fact declining as a result of third-party payers refusing to prescribe and/ or reimburse for off-label Subsys prescriptions as a result of Defendants’ illegal kickback scheme.

**C. False and Misleading Statements Concerning Insys’s Internal Controls Over Financial Reporting**

116. The 2015 Second Quarter Report also falsely represented that Insys maintained adequate controls over the Company’s financial reporting:

**ITEM 4. CONTROLS AND PROCEDURES**

**Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our President and Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of such date, ***our disclosure controls and procedures were effective.***

117. The 2015 Second Quarter Report also included certifications signed by Defendants Babich and Baker, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, identical to those in the 2015 First Quarter Report, which represented that Insys’s financial statements did not contain material misstatements or omissions, and that the Company employed internal disclosure controls over financial reporting and related disclosures.

118. The 2015 Second Quarter Report also contained certifications pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002, signed by Individual Defendants Babich and Baker identical to those in the 2015 First Quarter Report.

119. The above statements were materially false and misleading when made because: Defendants had admittedly: (i) understated revenue; (ii) understated rebate obligations to third-party payers, product returns by distributors, and Insys's overall provisions for sales allowance; (iii) as a result of (i) - (ii) Insys's internal controls over not effective but, rather, woefully inadequate.

#### **V. False and Misleading Statements in the November 5, 2015 Press Release**

120. On November 5, 2015, the Company issued a press release announcing its third quarter 2015 financial results for the three and nine-month period ended September 30, 2015. Touting Insys's "record results and our twelfth consecutive quarter of profitability at Insys," the Company reported the following quarter "highlights":

- Total net revenue increased to \$91.3 million compared to \$58.3 million for the third quarter of 2014;
- Revenue from Subsys<sup>®</sup> (fentanyl sublingual spray) was \$91.1 million, up 57% compared with third quarter 2014 revenue of \$58.2 million;
- Net income was \$26.1 million, or \$0.36 per basic and \$0.34 per diluted share, compared to net income of \$11.5 million, or \$0.17 per basic and \$0.16 per diluted share, for the third quarter of 2014.

121. Insys also reported net revenue and net income for the nine months ended September 30, 2015 of \$239.7 million and \$41.5 million, respectively.

122. The above statements were materially false and misleading when made because: Defendants had admittedly: (i) overstated revenue; (ii) understated rebate obligations to third-party payers, product returns by distributors, and Insys's overall provisions for sales allowance; (iii)

overstated earnings; (iv) as a result of (i) - (iii), Insys violated its own stated internal accounting policies for recording revenue, sales returns, rebates, and overall sales allowance; and, thus, (iv) the Company's business and prospects were worse than represented. Moreover, Defendants failed to disclose that sales of Subsys were, in fact declining as a result of third-party payers refusing to reimburse for off-label Subsys prescriptions as a result of Defendants' illegal kickback scheme.

123. Throughout the Class Period, the above material misstatements served to maintain the Company's inflated stock price. Indeed, as a result of the above misstatements, Insys's stock price increased 7.7 percent from \$25.43 per share on November 5, 2015 to close at \$27.39 per share on November 6, 2015.

## **VI. False and Misleading Statements in the 2015 Third Form 10-Q and Earnings Call**

124. On November 5, 2015, Insys filed its quarterly report on Form 10-Q with the SEC for the third quarter ended September 30, 2015 ("2015 Third Quarter Report"), which was signed and certified by Individual Defendants Kapoor and Baker. The 2015 Third Quarter Report contained materially false and misleading statements relating to Insys: (A) compliance with Company accounting policies; (B) financial statements and their compliance with GAAP; and (C) adequacy of internal controls and procedures.

### **A. False and Misleading Statements Concerning Compliance With Accounting Policies**

125. In the 2015 Third Quarter Report, Defendants falsely represented that Insys recognized revenue when four criteria were satisfied:

We recognize revenue from the sale of Subsys and Dronabinol SG Capsule. Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured.

126. With respect to sales allowances, Defendants falsely claimed that Insys recorded a product sales allowance at the same time revenue was recognized:

We recognize estimated product sales allowances as a reduction of product sales ***in the same period the related revenue is recognized.*** Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with customers and third-party payers and the levels of inventory within the distribution channels that may result in future discounts taken. In certain cases, such as patient assistance programs, we recognize the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, we may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment.

127. Defendants similarly misrepresented that Insys recorded product rebates at the time revenue was recognized:

***"Rebates.*** We participate in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, we pay a rebate to the third-party administrator of the program, generally two to three months after the quarter in which prescriptions subject to the rebate are filled. We estimate and accrue these rebates based on current contract prices, historical and estimated future percentages of products sold to qualified patients and estimated levels of inventory in the distribution channel. ***Estimated rebates are recognized as a reduction of revenue in the period the related revenue is recognized.*** The allowance for rebates is included in accrued sales allowances."

128. With respect to product returns, Defendants falsely represented that Insys has a reasonable basis with which to estimate returns:

***Product Returns.*** We allow customers to return product for credit beginning six months prior to, and ending 12 months following, the product expiration date. The shelf life of Subsys is currently 36 months from the date of manufacture. We have monitored actual return history since product launch, which ***provides us with a basis to reasonably estimate future product returns,*** taking into consideration the shelf life of product at the time of shipment, shipment and prescription trends, estimated distribution channel inventory levels, and consideration of the introduction of competitive products.

Because of the shelf life of our products and our return policy of issuing credits on returned product that is within six months before and up to 12 months after the product expiration date, there may be a significant period of time between when the product is shipped and when we issue credits on returned product. Accordingly, we may have to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustments. ***The allowance for product returns is included in accrued sales allowances.***

129. The above statements were materially false and misleading when made because Insys: (i) improperly recorded revenue before it was earned; (ii) failed to properly reserve for product returns and rebates; (iii) as a result of (i) and (ii) lacked any reasonable basis for estimating its sales allowance; (iv) Insys violated that Company's own internal accounting policies; and (v) lacked the appropriate processes and controls to properly track product returns and rebates.

**B. False and Misleading Statements Concerning Insys's Financial Statements and Compliance With GAAP**

130. In the 2015 Third Quarter Report, the Company reported net revenue for the three and nine months-ended September 30, 2015 of \$91.3 million and \$239.7 million, respectively. Insys also reported net income for the three and nine months of \$26.1 million and \$41.5 million, respectively.

131. Insys also reported provisions for wholesaler discounts, patient discounts, rebates and returns of increased to \$10.0 million, \$13.1 million, \$16.6 million and \$1.3 million, respectively, from the sale of Subsys for the three months ended September 30, 2015.

132. Also on November 5, 2015, the Company held an earnings call to discuss the recently announced third quarter 2015 financial results. Therein, Defendant Baker reported the same materially false and misleading statements as the 2015 Third Quarter Report:

Insys achieved a record quarter with total net revenue of \$91.3 million, which was an increase of 57% compared with the \$58.3 million we reported in the third quarter of 2014. . . .

GAAP net income for the third quarter of 2015 was \$26.1 million or \$0.34 per diluted share, compared to net income of \$11.5 million or \$0.16 per diluted share for the third quarter of 2014. Non-GAAP adjusted net income per diluted share for the third quarter of 2015 with \$0.50 compared to \$0.32 per diluted share for the third quarter of 2014.

133. In response to a question by one analyst from Randall Stanicky regarding the “growth outlook for Subsys”, Defendant Kapoor responded: “we look forward to growth of Subsys, maybe not as fast as has been in the past, but still it will be a growth product for us.”

134. The 2015 Third Quarter Report also falsely represented that “[t]he accompanying condensed consolidated financial statements are unaudited and have been prepared in accordance with U.S. generally accepted accounting principles, pursuant to rules and regulations of the Securities and Exchange Commission (the “SEC”).”

135. The above statements were materially false and misleading when made because: Defendants had admittedly: (i) overstated revenue; (ii) understated rebate obligations to third-party payers, product returns by distributors, and Insys’s overall provisions for sales allowance; (iii) overstated earnings; (iv) as a result of (i) - (iii) Insys’s financial statements were not in compliance with GAAP; and (v) Insys’s business and prospects were worse than represented. Moreover, Defendants failed to disclose that sales of Subsys were, in fact declining as a result of third-party payers refusing to reimburse for off-label Subsys prescriptions as a result of Defendants’ illegal kickback scheme.

**C. False and Misleading Statements Concerning Insys’s Internal Controls Over Financial Reporting**

136. The 2015 Third Quarter Report also falsely represented that Insys maintained adequate controls over the Company’s financial reporting:

**ITEM 4. CONTROLS AND PROCEDURES**

**Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our President and Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our Chief Executive Officer and

Chief Financial Officer have concluded that, as of such date, *our disclosure controls and procedures were effective.*

137. The 2015 Third Quarter Report also included certifications signed by Defendants Kapoor and Baker, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, nearly identical to those in the 2015 First Quarter Report, which represented that Insys's financial statements did not contain material misstatements or omissions, and that the Company employed internal disclosure controls over financial reporting and related disclosures.

138. The 2015 Second Quarter Report also contained certifications pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002, signed by Individual Defendants Kapoor and Baker nearly identical to those in the 2015 First Quarter Report.

139. The above statements were materially false and misleading when made because: Defendants had admittedly: (i) overstated revenue; (ii) understated rebate obligations to third-party payers, product returns by distributors, and Insys's overall provisions for sales allowance; (iii) overstated earnings; (iv) as a result of (i) - (ii) Insys's internal controls over not effective but, rather, woefully inadequate.

140. Throughout the Class Period, the above material misstatements served to maintain the Company's inflated stock price. Indeed, as a result of the above misstatements, Insys's stock price increased 7.7 percent from \$25.43 per share on November 5, 2015 to close at \$27.39 per share on November 6, 2015.

## **VII. False and Misleading Statements in the February 23, 2016 Press Release**

141. On February 23, 2016, the Company issued a press release announcing its fourth quarter and full-year 2015 financial results for the three-and twelve-month periods ended December 31, 2015. Touting Insys's "solid growth coupled with steady R&D progress," the Company reported the following relevant quarter "highlights":

- Total net revenue increased to \$91.1 million, compared to \$66.5 million for the fourth quarter of 2014;
- Revenue from Subsys® (fentanyl sublingual spray) was \$91.1 million, up 38% compared with fourth quarter 2014 revenue of \$66.1 million;
- Net income was \$17.0 million, or \$0.24 per basic and \$0.22 per diluted share, compared to net income of \$9.3 million, or \$0.13 per basic and diluted share, for the fourth quarter of 2014;

142. With respect to the Company's full year results, Defendants falsely reported in the 2015 Annual Report:

### ***2015 Financial Results***

Net revenue for the year ended December 31, 2015 was \$330.8 million compared to \$222.1 million for the year ended December 31, 2014, an increase of 49%.

Gross margin for 2015 was 91%, compared with 90% for 2014.

\*\*\*

Net income for 2015 was \$58.5 million, or \$0.82 per basic and \$0.77 per diluted share, compared to net income of \$38.0 million, or \$0.55 per basic and \$0.52 per diluted share, for 2014. Non-GAAP adjusted net income, which adjusts for non-cash stock compensation expense and non-cash income tax expense, was \$104.2 million, or \$1.38 per diluted share, compared to \$78.7 million, or \$1.07 per diluted share, in the prior year. The reconciliation of net income to Non-GAAP adjusted net income is included at the end of this press release.

143. The above statements were materially false and misleading when made because:

Defendants had admittedly: (i) overstated revenue; (ii) understated rebate obligations to third-party payers, product returns by distributors, and Insys's overall provisions for sales allowance; (iii) overstated earnings; (v) as a result of (i) - (iii), Insys violated its own stated internal accounting policies for recording revenue, sales returns, rebates, and overall sales allowance; and, thus, (v) the Company's business and prospects were worse than represented. Moreover, Defendants failed to disclose that sales of Subsys were, in fact declining as a result of third-party payers refusing to reimburse for off-label Subsys prescriptions as a result of Defendants' illegal kickback scheme.

144. Throughout the Class Period, the above material misstatements served to maintain the Company's inflated stock price. Indeed, as a result of the above misstatements, Insys's stock price increased 6.2 percent from \$26.21 per share on February 20, 2015 to close at \$27.83 per share on February 24, 2015.

### **VIII. False and Misleading Statements in the 2015 Annual Report and Earnings Call**

145. On February 29, 2016, Insys filed the 2015 Annual Report, which was signed and certified by Individual Defendants Kapoor and Baker. The 2015 Annual Report contained materially false and misleading statements relating to Insys: (A) compliance with Company accounting policies; (B) financial statements and their compliance with GAAP; and (C) adequacy of internal controls and procedures.

#### **A. False and Misleading Statements Concerning Compliance With Accounting Policies**

146. In the 2015 Annual Report, Defendants falsely represented that Insys recognized revenue when four criteria were satisfied:

We recognize revenue from the sale of Subsys and Dronabinol SG Capsule. Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured.

147. With respect to sales allowances, Defendants falsely claimed that Insys recorded a product sales allowance at the same time revenue was recognized:

We recognize estimated product sales allowances as a reduction of product sales ***in the same period the related revenue is recognized***. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with customers and third-party payers and the levels of inventory within the distribution channels that may result in future discounts taken. In certain cases, such as patient assistance programs, we recognize the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, we may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment.

148. Defendants similarly misrepresented that Insys recorded product rebates at the time revenue was recognized:

*Rebates.* We participate in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, we pay a rebate to the third-party administrator of the program, generally two to three months after the quarter in which prescriptions subject to the rebate are filled. We estimate and accrue these rebates based on current contract prices, historical and estimated future percentages of products sold to qualified patients and estimated levels of inventory in the distribution channel. ***The allowance for rebates is included in accrued sales allowances.***

149. With respect to product returns, Defendants falsely represented that Insys has a reasonable basis with which to estimate returns:

*Product Returns.* We allow customers to return product for credit on returned product that is within six months before and up to 12 months following its product expiration date. The shelf life of Subsys is currently 36 months from the date of manufacture. We have monitored actual product sold through patient prescriptions since product launch, ***which provides us with a basis to reasonably estimate future product returns,*** taking into consideration the shelf life of product at the time of shipment, shipment and prescription trends, estimated distribution channel inventory levels, and consideration of the introduction of competitive products.

Because of the shelf life of our products and our return policy of issuing credits on returned product that is within six months before and up to 12 months after its product expiration date, there may be a significant period of time between when the product is shipped and when we issue credits on returned product. Accordingly, we may have to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustments. ***The allowance for product returns is included in accrued sales allowances.***

150. The above statements were materially false and misleading when made because Insys: (i) improperly recorded revenue before it was earned; (ii) failed to properly reserve for product returns and rebates; (iii) as a result of (i) and (ii) lacked any reasonable basis for estimating its sales allowance; (iv) Insys violated that Company's own internal accounting policies; and (v) lacked the appropriate processes and controls to properly track product returns and rebates.

**B. False and Misleading Statements Concerning Insys's Financial Statements and Compliance With GAAP**

151. In the 2015 Annual Report, the Company reported net revenue and net income for the year-ended December 31, 2015 of \$330.8 million and \$58.5 million, respectively:

**Net Revenue.** Net revenue increased \$108.7 million, or 49%, to \$330.8 million for the year ended December 31, 2015, compared to \$222.1 million for the year ended December 31, 2014. *The increase in net revenue was primarily attributable to the \$109.9 million, or 50%, increase in net revenue of Subsys to \$329.5 million for the year ended December 31, 2015* compared to \$219.5 million for the year ended December 31, 2014. *The increase in Subsys revenue is primarily as a result of a 30% increase in shipments to pharmaceutical wholesalers and retailers for the year ended December 31, 2015* as compared to the year ended December 31, 2014, as well as a 20% increase in net sales price, which was impacted by price increases in January 2014, April 2014, July 2014, January 2015 and July 2015, combined with changes in mix of prescribed dosages and changes in provisions for wholesaler discounts, patient discounts, rebates and returns.

\* \* \*

We expect net revenue from sales of Subsys to continue to increase during 2016 due primarily to anticipated increases in unit prices and in the number of prescriptions fulfilled, combined with changes in prescription strength mix.

152. Insys also reported a provision for discounts, rebates and returns of \$36.8 million:

Provisions for wholesaler discounts, patient discounts, rebates and returns increased to \$36.8 million, \$61.0 million, \$63.0 million and \$3.3 million, respectively, or 33.2% on a combined basis of gross revenue from the sale of Subsys for the year ended December 31, 2014, compared to \$22.4 million, \$36.5 million, \$24.4 million and \$2.8 million, respectively, or 39.2% on a combined basis of gross revenue from the sale of Subsys for the year ended December 31, 2013. The increase in revenue provisions as a percentage of gross revenue was primarily attributable to an increase in the issuance of patient discount credits and rebate claims from managed care organizations and government programs.

153. Further, Defendants falsely reported for the year-ended December 31, 2015,

Revenue Allowance of \$39.1 million, Rebates of \$22.4 million and Returns of \$3.2 million:

	<b>Wholesale Discounts<sup>(1)</sup></b>	<b>Patient Programs</b>	<b>Rebates</b>	<b>Returns</b>	<b>Total</b>
Balance at December 31, 2014	\$ 5,418	\$ 2,227	\$ 7,910	\$ 1,159	\$ 16,714

Provision related to current period sales	36,849	60,991	63,402	3,158	164,400
Provisions related to sales made in prior years	-	-	(367)	138	(229)
Payment and credits related to sales made in current period	(30,480)	(53,848)	(41,030)	-	(125,358)
Payment and credits related to sales made in prior periods	(5,418)	(2,227)	(7,543)	(1,257)	(16,445)
Balance at December 31, 2015	\$ 6,369	\$ 7,143	\$ 22,372	\$ 3,198	\$ 39,082

(1) Includes wholesaler discounts, prompt pay discounts, stocking allowances and government chargebacks.

154. Also on February 23, 2016, the Company held an earnings call to discuss the recently announced full-year 2015 results. Therein, Defendant Baker falsely reported the same materially false and misleading statements as contained in the 2015 Annual Report and reported the following false statements for the fourth quarter-ended December 31, 2015:

Insys achieved a solid fourth quarter, with total net revenue of \$91.1 million, an increase of 37%, as compared with \$66.5 million for the fourth quarter of 2014. We generated adjusted EBITDA of \$39.3 million in the quarter. GAAP net income for the fourth quarter of 2015 was \$17 million, or \$0.22 per diluted share, compared to net income of \$9.3 million, or \$0.13 per diluted share for the fourth quarter of 2014. Non-GAAP adjusted net income per diluted share for the fourth quarter of 2015 was \$0.36, compared to \$0.26 per diluted share for the fourth quarter of 2014.

155. Further, when asked by an analyst on the call from Robert Sussman about the reason for the decline in Subsys scripts, Defendant Kapoor falsely blamed it on seasonality

Q: "Can you give us an idea of how many the Subsys scripts are down fourth quarter to first? And second is you're cutting back the marketing expenses for Subsys, and you indicated some loss of market share, which is very contrary to what the recent history has been. Is that because of Optum, or are there other reasons that you might be losing market share?"

A: Defendant Baker stating:

"I think to comment on your expenses, marketing expenses, we believe that we are spending wisely, and there's some readjustment on our expenditure on the speaker program, which speaker programs are heavily weighted when you launch a product and as time goes on, they tend to slow down, and that's what we did. We don't think that has anything to do with the market share. On the decline, I think what

seasonally in the first quarter, a lot of plans go through reauthorization and things like that, so it has some impact on the script, just because of the seasonality in the first quarter.

So I'm sure we're having some impact from that, some impact from Optum, some impact from the TIRF category, and I don't have to tell you that the publicity, the onslaught of sometimes misinformation have as well. So it's a combination of all of those factors. We are very conscious about it. We are very focused on it and we're working very hard on it. Our challenge as a team, a management team is to stabilize and change the trajectory of Subsys, and I can assure you that is job one in this Company. We meet every day, all of the management team address the issues of Subsys, and address them right away."

156. The 2015 Annual Report also falsely represented that financial statements were prepared in accordance with GAAP, stating: "the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Insys Therapeutics, Inc. at December 31, 2015 and 2014, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with accounting principles generally accepted in the United States of America."

157. The above statements were materially false and misleading when made because: Defendants had admittedly: (i) overstated revenue; (ii) understated rebate obligations to third-party payers, product returns by distributors, and Insys's overall provisions for sales allowance; (iii) overstated earnings; (iv) as a result of (i) - (iii), Insys's financial statements were not in compliance with GAAP; (v) improperly recorded an out-of-period adjustment related to a stock option modification previously recorded during the three months ended March 31, 2016 that related to the fourth quarter of 2015, resulting in a restated \$1.5 million increase in operating expenses during the three months ended December 31, 2015; and (vi) Insys's business and prospects were worse than represented. Moreover, Defendants failed to disclose that sales of Subsys were, in fact declining as a result of third-party payers refusing to reimburse for off-label Subsys prescriptions as a result of Defendants' illegal kickback scheme.

**C. False and Misleading Statements Concerning Insys's Internal Controls Over Financial Reporting**

158. In the 2015 Annual Report, Defendants made a startling admission that the Company lacked adequate internal controls regarding its "accounting for stock option awards," but failed to disclose the Company's inadequate controls over financial reporting relating to sales rebates and returns:

During the quarterly period ending December 31, 2015, we identified a material weakness in our internal control over financial reporting regarding the accounting for stock option awards. There were no other changes in our internal control over financial reporting as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f) that occurred during the quarterly period ended December 31, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Thus, while Defendants acknowledged a limited deficiency with respect to stock option awards, they also expressly assured investors "[t]here were no other changes in our internal controls," and further stated:

While we expect to take the measures necessary to address the underlying causes of this material weakness, we cannot at this time estimate how long it will take and our efforts may not prove to be successful in remediating this material weakness. While we have not incurred and do not expect to incur material expenses specifically related to the remediation of this material weakness, actual expenses may exceed our current estimates and overall costs of compiling the system and processing documentation necessary to assess the effectiveness of our internal control over financial reporting may be material.

159. The 2015 Report also included certifications signed by Defendants Kapoor and Baker pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 nearly identical to those included in the 2015 First Quarter Report, which represented that Insys's financial statements did not contain material misstatements or omissions, and that the Company employed internal disclosure controls over financial reporting and related disclosures.

160. The 2015 Annual Report contained a separate certification signed by Defendants Babich and Baker nearly identical to those contained in the 2015 First Quarter 2015 pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002.

161. The 2015 Annual report was signed by Defendants Kapoor, and Baker.

162. The above statements were materially false and misleading when made because: Defendants had admittedly: (i) overstated revenue; (ii) understated rebate obligations to third-party payers, product returns by distributors, and Insys's overall provisions for sales allowance; (iii) overstated earnings; (vi) as a result of (i) - (iii) Insys's internal controls over not effective but, rather, woefully inadequate.

## **IX. False and Misleading Statements in the April 28, 2016 Press Release**

163. On April 28, 2016, the Company issued a press release announcing Insys's first quarter 2016 financial results for the three-month period ended March 31, 2016, reporting the following relevant first quarter "highlights":

- Total net revenue decreased to \$62.0 million, compared to \$70.8 million for the first quarter of 2015;
- Revenue from Subsys® (fentanyl sublingual spray) was \$62.0, down 12% compared with first quarter 2015 revenue of \$70.5 million;
- Net income was \$2.4 million, or \$0.03 per basic and \$0.03 per diluted share, compared to net income of \$8.0 million, or \$0.11 per basic and \$0.11 per diluted share, for the first quarter of 2015.

164. Defendants blamed the decrease in revenue quarter over quarter on "a decline in Subsys demand, as Subsys prescription volumes were down, as well as a reduction in Subsys wholesale channel inventory levels." Later, on May 5, 2016, the Company held an earnings call with analysts in which Defendant Vetticaden falsely represented, *inter alia*:

So as a company, right, we are focused on addressing unmet medical needs. That's our number one criteria. So, if you look at all of our products, you look and see, is

there a need, and is there differentiated product that we could bring to address that need? And Subsys is a good example of that, right? Rapid-onset, [and SSI meds], especially for patients with cancer breakthrough pain. That's an important distinction when you're suffering with pain.

165. The above statements were materially false and misleading when made because:

Defendants had admittedly: (i) overstated revenue; (ii) understated rebate obligations to third-party payers, product returns by distributors, and Insys's overall provisions for sales allowance; (iii) overstated earnings; (iv) improperly recorded an out-of-period adjustment related to a stock option modification previously recorded during the three months ended March 31, 2016 that related to the fourth quarter of 2015, resulting in a restated \$1.5 million increase in operating expenses during the three months ended December 31, 2015; (v) as a result of (i) - (iv), Insys violated its own stated internal accounting policies for recording revenue, sales returns, rebates, and overall sales allowance; and, thus, (vi) the Company's business and prospects were worse than represented. Moreover, Defendants failed to disclose that sales of Subsys were, in fact declining as a result of third-party payers refusing to reimburse for off-label Subsys prescriptions as a result of Defendants' illegal kickback scheme.

#### **X. False and Misleading Statements in the 2016 First Quarter Form 10-Q and Earnings Call**

166. On May 5, 2016, Insys filed its quarterly report for the first quarter of 2016 on Form 10-Q for the period ended March 31, 2016 ("2016 First Quarter Report") with the SEC, which was signed and certified by Individual Defendants Kapoor and Baker. The 2016 First Quarter Report contained materially false and misleading statements relating to Insys: (A) compliance with Company accounting policies; (B) financial statements and their compliance with GAAP; and (C) adequacy of internal controls and procedures.

#### A. False and Misleading Statements Concerning Compliance With Accounting Policies

167. In the 2016 First Quarter Report, Defendants falsely represented that Insys recognized revenue when four criteria were satisfied:

We recognize revenue from the sale of Subsys and Dronabinol SG Capsule. Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured.

168. With respect to sales allowances, Defendants falsely claimed that Insys recorded a product sales allowance at the same time revenue was recognized:

We recognize estimated product sales allowances as a reduction of product sales ***in the same period the related revenue is recognized.*** Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with customers and third-party payers and the levels of inventory within the distribution channels that may result in future discounts taken. In certain cases, such as patient assistance programs, we recognize the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, we may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment.

169. Defendants similarly misrepresented that Insys recorded product rebates at the time revenue was recognized:

***Rebates.*** We participate in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, we pay a rebate to the third-party administrator of the program, generally two to three months after the quarter in which prescriptions subject to the rebate are filled. We estimate and accrue these rebates based on current contract prices, historical and estimated future percentages of products sold to qualified patients and estimated levels of inventory in the distribution channel. ***The allowance for rebates is included in accrued sales allowances.***

170. With respect to product returns, Defendants falsely represented that Insys has a reasonable basis with which to estimate returns:

***Product Returns.*** We allow customers to return product for credit beginning six months prior to, and ending 12 months following, the product expiration date. The shelf life of Subsys is currently 36 months from the date of manufacture. We have monitored actual return history since product launch, ***which provides us with a basis to reasonably estimate future product returns,*** taking into consideration the

shelf life of product at the time of shipment, shipment and prescription trends, estimated distribution channel inventory levels, and consideration of the introduction of competitive products.

Because of the shelf life of our products and our return policy of issuing credits on returned product that is within six months before and up to 12 months after the product expiration date, there may be a significant period of time between when the product is shipped and when we issue credits on returned product. Accordingly, we may have to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustments. ***The allowance for product returns is included in accrued sales allowances.***

171. The above statements were materially false and misleading when made because Insys: (i) improperly recorded revenue before it was earned; (ii) failed to properly reserve for product returns and rebates; (iii) as a result of (i) and (ii) lacked any reasonable basis for estimating its sales allowance; (iv) Insys violated that Company's own internal accounting policies; and (v) lacked the appropriate processes and controls to properly track product returns and rebates.

**B. False and Misleading Statements Concerning Insys's Financial Statements and Compliance With GAAP**

172. In the 2016 First Quarter Report, the Company reported net revenue and net income for the first quarter 2016 of \$62.0 million and \$2.4 million, respectively.

173. Insys also reported provisions for wholesaler discounts, patient discounts, rebates and returns of \$6.4 million, \$16.1 million, \$7.2 million and (\$0.5) million, respectively, or 32.0% on a combined basis of gross revenue from the sale of Subsys for the three months ended March 31, 2016.

174. The 2016 First Quarter Report also falsely represented that “[t]he accompanying condensed consolidated financial statements are unaudited and have been prepared in accordance with U.S. generally accepted accounting principles, pursuant to rules and regulations of the Securities and Exchange Commission (the “SEC”).”

175. Also on May 5, 2016, the Company held an earnings call to discuss the recently announced first quarter 2016 financial results. There, Defendant Baker falsely reported the same materially false and misleading financial statements:

Let me give just a little bit of color with respect to kind of our current situation with Subsys. What we saw in the first quarter of 2016, a market decline in Subsys scripts, about a 23% decline in scripts in Q1 of 2016 relative to Q4 of 2015, and about a 31% decline in revenue due to some deleveraging in the wholesale inventory channel. **We have seen recently what we believe stabilization in Subsys script trends.** Our market share in the TIRF class has maintained in the mid-40% range, but there has been a decline in the overall TIRF class. **But, given the most recent 12-week trend that we've observed, we believe that those trends have stabilized.**

And so, whereas we reported about \$62 million in Q1 of 2016 with about a \$7 million de-lever in the channel **puts us on a roughly \$70 million per quarter revenue run rate for Subsys currently.** We were profitable at the \$62 million revenue for Q1, all the while reaffirming our commitment to advancing our pipeline and maintaining profitability. . . .

176. When asked by an analyst from Greg Fraser about the Subsys payer coverage, Defendant Baker acknowledged that third-party payers were more reluctant to reimburse for Subsys:

Q: “[C]an you discuss what payer coverage looks like for this year? Maybe compare that with last year?”

A: “Yes, so, as I think the market is well aware, we had -- when we launched Subsys we had contracted with Optum, we were the preferred product on the Optum formulary in the TIRF class. In exchange for that placement, we were paying a very substantial rebate, and we made a decision, it was a financially-driven decision, to terminate our contract with Optum. As we've played that out here, effective January 1, it's been actually a net positive for us financially to no longer be paying that rebate to Optum. We are under contract with CVS, Cigna, and maintain good payer relationships with them.

You know, the payer landscape in 2016 has been -- **and I think it's not unique to our product or even to our class**, I think it's across-the-board, payers are -- **they seem to be digging their heels in a little bit in 2016, making it difficult for patients to get reimbursed, especially for specialty-type products such as Subsys.** But, we remain committed to, as we always have, patient access. And so, to the extent that the payers are uncooperative, we continue to partner with physicians and patients to ensure that they have access to the medication that they need and continue to

maintain dialogue with the payer community to remind them of the medical needs that are being served for the patients that they have a contract with.

And so, we're on the forefront of managing those payer relationships, as well as again primary focus is on ensuring that the patients get access to the care that they need."

177. Later, Fraser inquired as to how much off-label Subsys prescriptions had been occurring and whether that numbers had decreased recently in light of continued regulatory and third-party pressures, to which Defendant Baker responded: "Yes, there have been some studies conducted, that the FDA has asked the REMS, specifically, as a class-wide REMS, to conduct. And there has been an observed level of off-label use in the category... think it's been -- ***based on what I've seen, fairly consistent.*** At least since Subsys has been on the market."

178. The above statements were materially false and misleading when made because: Defendants had admittedly: (i) overstated revenue; (ii) understated rebate obligations to third-party payers, product returns by distributors, and Insys's overall provisions for sales allowances; (iii) overstated earnings; (iv) improperly recorded an out-of-period adjustment related to a stock option modification previously recorded during the three months ended March 31, 2016 that related to the fourth quarter of 2015, resulting in a restated \$1.5 million increase in operating expenses during the three months ended December 31, 2015; (v) as a result of (i) - (iv) Insys's financial statements were not in compliance with GAAP; and (vi) Insys's business and prospects were worse than represented. Moreover, Defendants failed to disclose the true extent that sales of Subsys were declining as a result of third-party payers refusing to reimburse for off-label Subsys prescriptions as a result of Defendants' illegal kickback scheme.

### C. False and Misleading Statements Concerning Insys's Internal Controls Over Financial Reporting

179. The 2016 First Quarter Report also falsely represented that Insys maintained adequate controls over the Company's financial reporting:

## ITEM 4. CONTROLS AND PROCEDURES

### Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our President and Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, and in light of the unremediated material weakness in the design and operation of our internal control over financial reporting relating specifically to the lack of effective policies and procedures, and effective reviews by personnel at an appropriate level, for accounting for stock options awards in accordance with GAAP, as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015, our Chief Executive Officer and Chief Financial Officer have concluded that, as of such date, our disclosure controls and procedures were not effective. To address this material weakness, we have taken steps to address the underlying causes of the material weakness as described further below under “Remediation Efforts to Address Material Weakness in Internal Control over Financial Reporting.” Accordingly, *we believe that the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q do fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented.*

180. The 2016 First Quarter Report also included certifications signed by Kapoor and Baker, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 nearly identical to those contained in the 2015 First Quarter Report, which represented that Insys’s financial statements did not contain material misstatements or omissions, and that the Company employed internal disclosure controls over financial reporting and related disclosures.

181. In addition, the 2016 First Quarter Report contained a separate certification signed by Defendants Kapoor and Baker nearly identical to those contained in the 2015 First Quarter Report, pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002.

182. With respect to the previously admitted internal control deficiency related to Insys’s accounting for stock options awards, Defendants assured investors that management had “taken steps to address the underlying causes of the material weakness.”

Our management, with the participation of our President and Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, and in light of the unremediated material weakness in the design and operation of our internal control over financial reporting *relating specifically to the lack of effective policies and procedures, and effective reviews by personnel at an appropriate level, for accounting for stock options awards in accordance with GAAP*, as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015, our Chief Executive Officer and Chief Financial Officer have concluded that, as of such date, *our disclosure controls and procedures were not effective*. To address this material weakness, we have taken steps to address the underlying causes of the material weakness as described further below under “Remediation Efforts to Address Material Weakness in Internal Control over Financial Reporting.” Accordingly, we believe that the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q *do fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented*.

183. The above statements were materially false and misleading when made because:

Defendants had admittedly: (i) overstated revenue; (ii) understated rebate obligations to third-party payers, product returns by distributors, and Insys’s overall provisions for sales allowance; (iii) overstated earnings; (iv) as a result of (i) - (iii) Insys’s internal controls over not effective but, rather, woefully inadequate; and, thus, (v) the Company’s 2016 First Quarter Report did not accurately present Insys’s financial position.

## **XI. False and Misleading Statements in the August 3, 2016 Press Release and Earnings Call**

184. On August 3, 2016, the Company issued a press release announcing its second quarter 2016 financial results for the three-month period ended June 30, 2016, reporting the following relevant quarter “highlights”:

- Total net revenue was \$67.1 million, compared to \$77.6 million for the second quarter of 2015;
- Net income totaled \$4.4 million, or \$0.06 per basic and \$0.06 per diluted share, compared to net income of \$7.3 million, or \$0.10 per basic and \$0.10 per diluted

share, for the second quarter of 2015.

185. Defendants further stated that the decline in sales was the result of a decline in “Subsys prescription volumes due to softness in overall demand in the TIRF category, including Subsys, and continued pressure from third-party payers.”

186. Also on August 3, 2016, the Company held an earnings call to discuss the recently announced second quarter 2016 financial results wherein Defendant Baker falsely represented with respect to the Company’s financial performance, *inter alia*:

***Despite recent challenges, Insys remains profitable with a strong, debt-free balance sheet. We reported total net revenue of \$67.1 million for the second quarter of 2016, which was a decrease of 13.5% from the \$77.6 million in the quarter a year ago.*** As expected, SUBSYS prescription trends experienced softness in the second quarter of 2016. ***The decline in SUBSYS revenue was a reflection of the heightened publicity surrounding the national opioid epidemic and the resulting sensitivity by some health care providers who prescribe opioids.*** This sensitivity has affected the entire TIRF class. At current prescription levels, we expect to remain profitable and to continue to fund our R&D efforts.

GAAP net income for the second quarter of 2016 was \$4.4 million, or \$0.06 per diluted share, compared to net income of \$7.3 million, or \$0.10 per diluted share, for the second quarter of 2015. Non-GAAP adjusted net income per diluted share for the second quarter of 2016 was \$0.13 compared to \$0.21 per diluted share for the second quarter of 2015. Gross margin was 90.7% for the second quarter of 2016, compared with 89.3% for the comparable period in 2015.

187. When asked by one analyst from Piper Jaffray with respect to Subsys revenue reimbursements, Defendant Baker acknowledged pressure from third-party payers had caused a decline in Subsys revenues, while Defendant Kapoor assured investors that Insys would have no problem maintaining its market share:

Q: “[C]an you just talk about how we should think about the gross to net on SUBSYS through the back half of the year?”

A: Defendant Baker response:

“Our Q2 gross to net roughly -- is coming in at rough -- or netting roughly 60%. Historically, we had been at about two-thirds that we had netted. And, again, I think

the continued pressure from third-party payers has required us to step in and provide a little more support. We expect, David, that that will continue to be a challenge as we move throughout the balance of 2016, and we expect there to be further downward pressure on our revenue as a result of that as we move throughout the balance of the year and into 2017.”

Defendant Kapoor added:

“And ***we are confident that we can maintain the market share***, which we believe is very important to us.

\* \* \*

So there's a lot of activity that is going on in the SUBSYS space from us, and we believe we are the only company out there in TIRF market that's doing any research. So we think that eventually all that is going to help our SUBSYS sales. And, therefore, it's important for us to maintain the market share we have. And we believe we have the best product in the space with the features we have and the acceptability by the CPEs and the patients is huge. And so we will stay competitive.”

188. The above statements were materially false and misleading when made because:

Defendants had admittedly: (i) misstated revenue, rebate obligations to third-party payers, product returns by distributors, and Insys's overall provisions for sales allowance and earnings; (ii) as a result of (i), Insys violated its own stated internal accounting policies for recording revenue, sales returns, rebates, and overall sales allowance; and, thus, (iii) the Company's business and prospects were worse than represented. Moreover, Defendants failed to disclose that sales of Subsys were, in fact declining as a result of third-party payers refusing to prescribe and/ or reimburse for off-label Subsys prescriptions as a result of Defendants' illegal kickback scheme.

189. Throughout the Class Period, the above material misstatements served to maintain the Company's inflated stock price. Indeed, as a result of the above misstatements, Insys's stock price increased 17.4% from \$15.20 per share on August 2, 2016 to \$17.85 per share on August 3, 2016.

## **XII. False and Misleading Statements in the 2016 Second Quarter Report**

190. On August 5, 2016, Insys filed its quarterly report on Form 10-Q with the SEC for the second quarter ended June 30, 2016 (“2016 Second Quarter Report”), which was signed and certified by Individual Defendants Kapoor and Baker. The 2016 Second Quarter Report contained materially false and misleading statements relating to Insys: (A) compliance with Company accounting policies; (B) financial statements and their compliance with GAAP; and (C) adequacy of internal controls and procedures.

### **A. False and Misleading Statements Concerning Key Financial Metrics and Compliance With Internal Policies**

191. In the 2016 Second Quarter Report, Defendants falsely represented that Insys recognized revenue when four criteria were satisfied:

We recognize revenue from the sale of Subsys. Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured.

192. With respect to sales allowances, Defendants falsely claimed that Insys recorded a product sales allowance at the same time revenue was recognized:

We recognize estimated product sales allowances as a reduction of product sales ***in the same period the related revenue is recognized***. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with customers and third-party payors and the levels of inventory within the distribution channels that may result in future discounts taken. In certain cases, such as patient assistance programs, we recognize the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, we may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment.

193. Defendants similarly misrepresented that Insys recorded product rebates at the time revenue was recognized:

***Rebates.*** We participate in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, we pay a rebate to the third-party administrator of the program, generally two to three months

after the quarter in which prescriptions subject to the rebate are filled. We estimate and accrue these rebates based on current contract prices, historical and estimated future percentages of products sold to qualified patients and estimated levels of inventory in the distribution channel. The allowance for rebates is included in accrued sales allowances.”

194. With respect to product returns, Defendants falsely represented that Insys has a reasonable basis with which to estimate returns:

*Product Returns.* We allow customers to return product for credit within six months before and up to 12 months prior to, and ending 12 months following, the product expiration date. The shelf life of Subsys is currently 36 months from the date of manufacture. We have monitored actual return history since product launch, which **provides us with a basis to reasonably estimate future product returns**, taking into consideration the shelf life of product at the time of shipment, shipment and prescription trends, estimated distribution channel inventory levels, and consideration of the introduction of competitive products.

Because of the shelf life of our products and our return policy of issuing credits on returned product that is within six months before and up to 12 months after its product expiration date, there may be a significant period of time between when the product is shipped and when we issue credits on returned product. Accordingly, we may have to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustments. **The allowance for product returns is included in accrued sales allowances.**

195. The above statements were materially false and misleading when made because Insys: (i) improperly recorded revenue before it was earned; (ii) failed to reserve for product returns and rebates; (iii) as a result of (i) and (ii) lacked any reasonable basis for estimating its sales allowance; (iv) Insys violated that Company’s own internal accounting policies; and (v) lacked the appropriate processes and controls to properly track product returns and rebates

**B. False and Misleading Statements Concerning Insys’s Financial Statements and Compliance With GAAP**

196. In the 2016 Second Quarter Report, the Company reported net revenue for the three and six months ended June 30, 2016 of \$67.2 million and \$129.1 million, respectively. Insys also reported net income for the three and six months ended of \$4.4 million and \$7 million, respectively.

197. Insys also reported a provisions for wholesaler discounts, patient discounts, rebates and returns of \$24.1 million \$7.8 million, \$12.6 million and \$0.5 million, respectively, or 40.1% on a combined basis of gross revenue from the sale of Subsys for the three months ended June 30, 2016.

198. The 2016 Second Quarter Report also falsely represented that “[t]he accompanying condensed consolidated financial statements are unaudited and have been prepared in accordance with U.S. GAAP, pursuant to rules and regulations of the SEC.”

199. The above statements were materially false and misleading when made because: Defendants had admittedly: (i) materially misstated revenue, rebate obligations, product returns, Insys's provisions for sales allowance and earnings; (ii) as a result of (i), Insys's financial statements were not in compliance with GAAP; and (iii) Insys's business and prospects were worse than represented. Moreover, Defendants failed to disclose that sales of Subsys were, in fact declining as a result of third-party payers refusing to reimburse for off-label Subsys prescriptions as a result of Defendants' illegal kickback scheme Subsys prescriptions.

### **C. False and Misleading Statements Concerning Insys's Internal Controls Over Financial Reporting**

200. The 2016 Second Quarter Report also falsely represented that Insys maintained adequate controls over the Company's financial reporting:

#### **ITEM 4. CONTROLS AND PROCEDURES**

##### ***Evaluation of Disclosure Controls and Procedures***

Our management, with the participation of our President and Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, and in light of the un-remediated material weakness in the design and operation of our internal control over financial reporting relating specifically to the lack of effective policies and procedures, and effective reviews by personnel at an appropriate level, for accounting for stock

options awards in accordance with GAAP, as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were not effective. To address this material weakness, we have taken steps to address the underlying causes of the material weakness as described further below under “Remediation Efforts to Address Material Weakness in Internal Control over Financial Reporting.” Accordingly, we believe that the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q do fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented.

201. The 2016 Second Quarter Report also included certifications signed by the Defendants Kapoor and Baker, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 nearly identical to those contained in the 2015 First Quarter Report, which represented that Insys’s financial statements did not contain material misstatements or omissions, and that the Company employed internal disclosure controls over financial reporting and related disclosures.

202. The 2016 Second Quarter Report contained a separate certification signed by Defendants Kapoor and Baker pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002, nearly identical to those contained in the 2015 First Quarter Report.

203. With respect to the previously admitted internal control deficiency related to Insys’s accounting for stock options awards, Defendants assured investors that management had “taken steps to address the underlying causes of the material weakness:”

Our management, with the participation of our President and Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, and in light of the un-remediated material weakness in the design and operation of our internal control over financial reporting *relating specifically to the lack of effective policies and procedures, and effective reviews by personnel at an appropriate level, for accounting for stock options awards in accordance with GAAP*, as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015, our Chief Executive Officer and

Chief Financial Officer have concluded that, as of such date, *our disclosure controls and procedures were not effective*. To address this material weakness, we have taken steps to address the underlying causes of the material weakness as described further below under “Remediation Efforts to Address Material Weakness in Internal Control over Financial Reporting.” Accordingly, we believe that the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q *do fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented.*

204. The above statements were materially false and misleading when made because:

Defendants had admittedly: (i) materially misstated revenue, rebate obligations, returns, provisions for sales allowance and earnings; (ii) as a result of (i), Insys’s internal controls over not effective but, rather, woefully inadequate; and, thus, (iii) the Company’s 2016 Second Quarter Report did not accurately present Insys’s financial position.

### **XIII. False and Misleading Statements in the November 3, 2016 Press Release**

205. On November 3, 2016, the Company issued a press release announcing its third quarter 2016 financial results for the three and nine-month period ended September 30, 2016. Therein, the Company reported the following relevant quarter “highlights”:

- Total net revenue was \$55.2 million, compared to \$91.3 million for the third quarter of 2015;
- Net income totaled \$190,000, or \$0.00 per basic and \$0.00 per diluted share, compared to net income of \$26.1 million, or \$0.36 per basic and \$0.34 per diluted share, for the third quarter of 2015.

206. Defendant Kapoor lauded the results stating, for example: “[a]lthough Subsys volumes declined in the quarter, we are pleased to have maintained a mid-40% market share and believe the product will continue to provide a solid financial foundation for growth and to support our R&D efforts...We remain excited about our pipeline and believe that both our spray and cannabinoid platform products will provide opportunities for future growth.”

207. With respect to Subsys revenues, Defendants attributed the decline in sales to “a decline in Subsys prescription volumes due to softness in overall demand in the TIRF category, including Subsys, and continued pressure from third-party payers.”

208. Defendants also reported net revenue and net income for the nine-month period of \$184.3 million and \$7.0 million, respectively.

209. Also on November 3, 2016, the Company held an earnings call to discuss the recently announced second quarter 2016 financial results wherein Defendant Baker falsely represented with respect to the Company’s financial performance, *inter alia*:

[W]e reported net revenue of \$55.2 million for the third quarter of 2016, which was a decrease from the \$91.3 million in the year ago quarter. As expected, Subsys prescription trends experienced softness in the third quarter of 2016. ***The decline in Subsys revenue is the result of ongoing and heightened publicity surrounding the national opioid epidemic and continuing governmental and regulatory scrutiny of the Company and of the Transmucosal Immediate-Release Fentanyl or TIRF class, resulting in sensitivity by some healthcare providers to prescribe and dispense TIRF medications.***

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GAAP net income for the third quarter of 2016 was \$190,000 or \$0.00 per diluted share compared to net income of \$26 million or \$0.34 per diluted share for the third quarter of 2015. Non-GAAP adjusted net income per diluted share for the third quarter of 2016 was \$0.07 compared to \$0.50 per diluted share for the third quarter of 2015.

210. Further, when asked by an analyst from Piper Jaffray about “the gross net spreads for Subsys going forward” and “continued pressure on the overall TIRF market due to greater physician sensitivity to opioids,” Defendant Kapoor blamed Subsys decline to pressure on the overall TIRF class:

So with respect to the gross to nets, what we saw here in the third quarter was roughly 50% gross to net, which is the most challenged our gross to nets have ever been. We expect that as we move forward ***we're going to be able to make slight improvements to our gross to nets.*** With respect to the TIRF class overall there has been a lot of pressure on the class. There have been significant declines in the class. If you go back to when the REMS was implemented, about four years ago the TIRF class was roughly 10,000 per month. Today, the class is down to about 6,200 scripts

per month. We continue to maintain our share in the mid-40% range. So as the class goes kind of that's how Subsys goes. So we expect that there will be continued pressure on the class but we also believe that over time we are going to be able to see growth again in the TIRF class.

211. Defendant Vetticaden further falsely represented to analysts and investors that the Company was “committed to the appropriate use of opioids” and had “a moral imperative to contribute to solutions to address this opioid epidemic.” To this end, Defendant Vetticaden further stated: “one of our principal areas of expertise is in drug development and it is through these efforts that we believe we will be able to offer potential solutions to address some of the concerns associated with the opioid epidemic.”

212. The above statements were materially false and misleading when made because: Defendants had admittedly: (i) materially misstated revenue, rebate obligations, product returns, provisions for sales allowance and earnings; (ii) as a result of (i), Insys violated its own stated internal accounting policies for recording revenue, sales returns, rebates, and overall sales allowance; and, thus, (iii) the Company’s business and prospects were worse than represented. Moreover, Defendants failed to disclose that sales of Subsys were, in fact declining as a result of third-party payers refusing to reimburse for off-label prescriptions as a result of Defendants’ illegal kickback scheme involving Subsys.

213. Throughout the Class Period, the above material misstatements served to maintain the Company’s inflated stock price. Indeed, as a result of the above misstatements, Insys’s stock price increased 19.8% from \$10.02 per share on November 3, 2016 to \$11.99 per share on November 7, 2016.

#### **XIV. False and Misleading Statements in the 2016 Third Quarter Form 10-Q**

214. On November 3, 2016, Insys filed its quarterly report on Form 10-Q with the SEC for the third quarter ended September 30, 2016 (“2016 Third Quarter Report”) with the SEC, which

was signed and certified by Individual Defendants Kapoor and Baker. The 2016 Second Quarter Report contained materially false and misleading statements relating to Insys: (A) compliance with Company accounting policies; (B) financial statements and their compliance with GAAP; and (C) adequacy of internal controls and procedures.

**A. False and Misleading Statements Concerning Compliance With Accounting Policies**

215. In the 2016 Third Quarter Report, Defendants falsely represented that Insys recognized revenue when four criteria were satisfied:

We recognize revenue from the sale of Subsys. Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured.

216. With respect to sales allowances, Defendants falsely claimed that Insys recorded a product sales allowance at the same time revenue was recognized:

We recognize estimated product sales allowances as a reduction of product sales *in the same period the related revenue is recognized*. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with customers and third-party payors and the levels of inventory within the distribution channels that may result in future discounts taken. In certain cases, such as patient assistance programs, we recognize the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, we may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment.

217. Defendants similarly misrepresented that Insys recorded product rebates at the time revenue was recognized:

*Rebates.* We participate in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, we pay a rebate to the third-party administrator of the program, generally two to three months after the quarter in which prescriptions subject to the rebate are filled. We estimate and accrue these rebates based on current contract prices, historical and estimated future percentages of products sold to qualified patients and estimated levels of inventory in the distribution channel. The allowance for rebates is included in accrued sales allowances.

218. With respect to product returns, Defendants falsely represented that Insys has a reasonable basis with which to estimate returns:

*Product Returns.* We allow customers to return product for credit within six months before and up to 12 months prior to, and ending 12 months following, the product expiration date. The shelf life of Subsys is currently 36 months from the date of manufacture. We have monitored actual return history since product launch, which ***provides us with a basis to reasonably estimate future product returns***, taking into consideration the shelf life of product at the time of shipment, shipment and prescription trends, estimated distribution channel inventory levels, and consideration of the introduction of competitive products.

Because of the shelf life of our products and our return policy of issuing credits on returned product that is within six months before and up to 12 months after the product expiration date, there may be a significant period of time between when the product is shipped and when we issue credits on returned product. Accordingly, we may have to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustments. ***The allowance for product returns is included in accrued sales allowances.***

219. The above statements were materially false and misleading when made because Insys: (i) improperly recorded revenue before it was earned; (ii) failed to reserve for product returns and rebates; (iii) as a result of (i) and (ii) lacked any reasonable basis for estimating its sales allowance; (iv) Insys violated that Company's own internal accounting policies; and (v) lacked the appropriate processes and controls to properly track product returns and rebates.

#### **B. False and Misleading Statements Concerning Insys's Financial Statements and Compliance With GAAP**

220. In the 2016 Third Quarter Report, the Company reported net revenue for the three and nine months-ended September 30, 2016 of \$55.2 million and \$184.3 million, respectively. Insys also reported net income for the three and nine months of \$.19 million and \$7.0 million, respectively.

221. Insys also reported a provisions for wholesaler discounts, patient discounts, rebates and returns of \$33.6 million \$8.2 million, \$13.2 million and less than \$0.1 million, respectively,

or 49.9% on a combined basis of gross revenue from the sale of Subsys for the three months ended September 30, 2016.

222. The 2016 Third Quarter Report also falsely represented that “[t]he accompanying condensed consolidated financial statements are unaudited and have been prepared in accordance with U.S. GAAP, pursuant to rules and regulations of the SEC.”

223. The above statements were materially false and misleading when made because: Defendants had admittedly: (i) materially misstated revenue, rebate obligations, product returns, provisions for sales allowance and earnings; (ii) as a result of (i), Insys’s financial statements were not in compliance with GAAP; and (iii) Insys’s business and prospects were worse than represented. Moreover, Defendants failed to disclose that sales of Subsys were, in fact declining as a result of third-party payers refusing to reimburse for off-label Subsys prescriptions as a result of Defendants’ illegal kickback scheme.

### **C. False and Misleading Statements Concerning Insys’s Internal Controls Over Financial Reporting**

224. The 2016 Third Quarter Report also falsely represented that Insys maintained adequate controls over the Company’s financial reporting:

#### **ITEM 4. CONTROLS AND PROCEDURES**

##### *Evaluation of Disclosure Controls and Procedures*

Our management, with the participation of our President and Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, and in light of the un-remediated material weakness in the design and operation of our internal control over financial reporting relating specifically to the lack of effective policies and procedures, and effective reviews by personnel at an appropriate level, for accounting for stock options awards in accordance with GAAP, as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were

not effective. To address this material weakness, we have taken steps to address the underlying causes of the material weakness as described further below under “Remediation Efforts to Address Material Weakness in Internal Control over Financial Reporting.” Accordingly, we believe that the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q do fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented.

225. The 2016 Third Quarter Report also included certifications signed by Defendants Baker and Kapoor, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 nearly identical to those contained in the 2015 First Quarter Report, which represented that Insys’s financial statements did not contain material misstatements or omissions, and that the Company employed internal disclosure controls over financial reporting and related disclosures.

226. The 2016 Third Quarter Report contained certifications pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002, signed by Defendants Kapoor and Baker that were nearly identical to those contained in the 2015 First Quarter Report.

227. With respect to the previously admitted internal control deficiency related to Insys’s accounting for stock options awards, Defendants assured investors that management had “taken steps to address the underlying causes of the material weakness:

Our management, with the participation of our President and Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, and in light of the un-remediated material weakness in the design and operation of our internal control over financial reporting *relating specifically to the lack of effective policies and procedures, and effective reviews by personnel at an appropriate level, for accounting for stock options awards in accordance with GAAP*, as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015, our Chief Executive Officer and Chief Financial Officer have concluded that, as of such date, *our disclosure controls and procedures were not effective*. To address this material weakness, we have taken steps to address the underlying causes of the material weakness as described further below under ‘Remediation Efforts to Address Material Weakness in Internal Control over Financial Reporting.’ Accordingly, we believe that the condensed consolidated financial statements included in this Quarterly Report on

Form 10-Q *do fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented.*

228. The above statements were materially false and misleading when made because: Defendants had admittedly: (i) materially misstated revenue, rebate obligations, returns, provisions for sales allowance and earnings; (ii) as a result of (i), Insys's internal controls over not effective but, rather, woefully inadequate; and, thus, (iii) the Company's 2016 Second Quarter Report did not accurately present Insys's financial position.

229. Throughout the Class Period, the above material misstatements served to maintain the Company's inflated stock price. Indeed, as a result of the above misstatements, Insys's stock price increased 19.8% from \$10.02 per share on November 3, 2016 to \$11.99 per share on November 7, 2016.

#### **THE TRUTH IS REVEALED**

230. Investors would ultimately learn the truth about Insys's business, operations, growth, financial statements, and financial condition when, on March 15, 2017, Insys announced that the Company would delay the release of its financial results for the fourth quarter and full year 2016. The March 15 press release revealed for the first time that the Insys Audit Committee had been investigating "the Company's processes related to estimation of, and increases to, certain sales allowances recorded during 2016, with a potential reduction of 2015 net revenue and pre-tax income not expected to exceed \$5 million, as well as extended payment terms offered to certain customers during the third quarter of 2016." According to the March 15 Press Release, "[t]he Company and the Audit Committee are working diligently to complete their review and the Company will make a *further* announcement regarding updated timing of its release of financial results and a related conference call once the review is completed."

231. As a result of this review, the Company had filed a notification of late filing on Form 12b-25 with the SEC to obtain an automatic 15-day extension of the filing deadline for its Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

232. Upon this news, the price of Insys common stock declined from a closing share price of \$10.55 on March 15, 2017 to \$10.06 at close on March 16, 2017, a loss of 4.64%, on heavy trading volume that was 37.4% higher than the prior day. In contrast, on March 16, 2017 the Nasdaq US Smart Pharma Index was *up* 1.6%.

#### **POST-CLASS PERIOD EVENTS**

233. Just two weeks after this investigation was disclosed, on March 31, 2017, Defendants reaffirmed Insys' March 15 announcement that informed investors the Company was engaging in material accounting manipulations relating to the recording of revenue and sales allowances. Specifically, Insys disclosed that the Audit Committee had concluded, upon the recommendation of Insys management, that the Company's previously issued interim unaudited condensed consolidated financial statements as of and for the quarters ended September 30, June 30, and March 31, 2016 and 2015, should no longer be relied upon, and those financial statements would be restated due to the identification of "***material***" errors. According to Defendants, the restatements resulted from errors related to the Company's accounting for certain of its product sales allowances. Defendants expressly acknowledged, among other things, that ***the impact of these errors was material***, and were the result of "***not display[ing] an adequate tone at the top*** ***amongst management***.

234. Further, Defendants confirmed that the Company's internal controls over financial reporting were not effective due to a material weakness in the design and operation of the internal controls over financial reporting relating specifically to the lack of effective policies and

procedures, or timely and effective reviews by personal at an appropriate level, for accounting for the rebates component in product sales allowances.

235. On April 7, 2017, Insys filed three Form 10-Q/A's materially modifying its quarterly reports for the quarters ended September 30, June 30, and March 31, 2016 and 2015. As reflected in the chart below, the restated financial metrics significantly increased the Company's product sales allowance on a quarter-over-quarter basis, including a \$3.507 million increase to accrued sales allowances in 2015:

(in millions)	Product Sales Allowance		Rebate Obligations		Net Revenue	
	Reported	Restated	Reported	Restated	Reported	Restated
March 31, 2015	15.2	21.3	8.4	11.5	70.8	67.7
June 30, 2015	17.6	20.3	16.8	13.4	77.6	80.2
September 30, 2015	25.6	31.9	16.6	20.1	91.3	88.5
March 31, 2016	24.9	29.7	7.2	8.3	62.0	60.4
June 30, 2016	30.4	31.7	12.6	9.3	67.1	69.2
September 30, 2016	41.8	41.8	13.2	11.9	55.1	57.8

236. Simultaneously, Insys recorded a \$3.033 million adjustment to net revenue in 2014 and \$474,000 adjustment in 2015, resulting from accounting improprieties concerning recording revenue from Subsys and reclassified portions of the revenue and expenses to 2016 which helped offset the otherwise adverse effect of the increase in sales allowances to net revenue for 2015 and 2016. Specifically, Insys increased net revenue \$3.152 million and increased net income \$4.263 million in 2016, as a result of a \$3.033 revision and decrease to net revenue in 2014 and \$474,000 decrease in 2015. Insys also reversed two out-of-period adjustments related to a stock option

modification and the deductible interest portion of an accrued litigation award. In particular, Insys failed to recognize the \$1.5 million operating expense during the three months ended December 31, 2015 and instead pushed the expenses to the subsequent three months ended March 31, 2016.

### **INSYS'S NUMEROUS GAAP VIOLATIONS**

237. As alleged above, during the Class Period, the Company issued financial statements that were materially misstated and not presented in accordance with GAAP. The SEC requires that publicly-traded companies such as Insys present their financial statements in accordance with GAAP. GAAP are a set of criteria used to determine measurement, recognition, presentation, and disclosure of all material items appearing in the financial statements.<sup>15</sup>

238. SEC regulation S-X (17 C.F.R. § 210.4-01 (a)(1)) provides that financial statements filed with the SEC, which are not presented in accordance with GAAP "*will be presumed to be misleading*, despite footnotes or other disclosures." Regulation S-X also requires that interim financial statements comply with GAAP, with the exception that interim financial statements need not include disclosures, which would be duplicative of disclosures accompanying annual financial statements. 17 C.F.R. § 210.01-01(a).

239. The responsibility for preparing financial statements (which include the footnotes to the financial statements) in conformity with GAAP rests with corporate management, as set forth in the Preface to the AICPA's Clarified Auditing Standards:

management and, when appropriate, those charged with governance, have responsibility[:]

- a. for the preparation and fair presentation of the financial statements in accordance with the applicable financial reporting framework;

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<sup>15</sup> American Institute of Certified Public Accountants ("AICPA") Auditing Standards Board ("ASB"), Auditing Standards – Clarified, Section ("AU-C") *Glossary of Terms*.

b. for the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error...<sup>16</sup>

240. Each of the improper accounting practices in which the Company engaged, as well as Defendants' misrepresentations and omissions, standing alone, was a material breach of GAAP, Company policy, and/or SEC regulations.

241. As discussed below, Insys's 2015 First Quarter Report, 2015 Second Quarter Report, 2015 Third Quarter Report, 2015 Annual Report, 2016 First Quarter Report, 2016 Second Quarter Report and 2016 Third Quarter Report (collectively, the "False and Misleading Financial Statements") violated GAAP by: (i) overstating revenue and earnings; (ii) understating rebates, returns and accrual for sales allowance; (iii) failing to adequately accrue for product returns and rebates; (iv) failing to appropriately record revenue when it was earned; and (v) failing to maintain sufficient internal controls over the financial reporting process to ensure the Company's financial statements were reported in compliance with GAAP.

## I. Insys Materially Misstated Net Revenue

242. Insys's revenue recognition policy states that "revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured." Defendants, however, did not comply with the policy. Rather, Defendants prematurely recognized revenue upon shipment to the distributor, instead of when the product was sold to the end user or the right of return had expired.

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<sup>16</sup> AU-C Preface – *Principles Underlying an Audit Conducted in Accordance with Generally Accepted Auditing Standards*.

243. The revenue recognition method that Insys employed was improper because the price was not fixed or determinable due to distributor's lengthy rights of return. Specifically, Insys consistently recorded revenue without meeting the criteria established by GAAP for recognizing revenue on such transactions which are set forth below:

- (a) FASB ASC 605-25 states that revenue is realized/realizable and earned when the following occur: (i) there is persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the seller's price to the buyer is fixed or determinable; and (iv) collectability is reasonably assured.
- (b) FASB Statement of Financial Accounting Standards No. 48, which provides that if an enterprise sells its product but gives the buyer the right to return the product, revenue from the sales transaction shall be recognized at time of sale only if all of the following conditions are met: (i) the seller's price to the buyer is substantially fixed or determinable at the date of sale; (ii) the buyer has paid the seller, or the buyer is obligated to pay the seller and the obligation is not contingent on resale of the product; (iii) the buyer's obligation to the seller would not be changed in the event of theft or physical destruction or damage of the product; (iv) the buyer acquiring the product for resale has economic substance apart from that provided by the seller; (v) the seller does not have significant obligations for future performance to directly bring about resale of the product by the buyer; (vi) the amount of future returns can be reasonably estimated.
- (c) FASB ASC 605-25, which states a vendor may offer a customer a rebate or refund of a specified amount of cash consideration, and the vendor shall recognize the rebate or refund obligation as a reduction of revenue based on a systematic and rational allocations of the cost of honoring the rebate or refunds. However, if the amount of future rebates or refunds cannot be reasonably estimated, a liability shall be recognized for the maximum potential amount of the refund or rebate. Any of the following factors may impair a vendor's ability to make a reasonable estimate:
  - a. Relatively long periods in which a particular rebate or refund may be claimed;
  - b. The absence of historical experience with similar types of sales incentive programs; or
  - c. The absence of a large volume of relatively homogeneous transactions.

244. These standards stipulate that revenue should not be recognized unless there is a fixed and determinable price, and future returns and rebates can be reasonably estimable. Insys disclosed in its 2016 Annual Report, that the Company "monitored actual return history since product launch, which provides us with a basis to reasonably estimate future product returns." The

product shelf life is 36 months, and Insys allows “customers to return product for credit within six months before and up to 12 months following its product expiration date.” Subsys was introduced into the market in 2012, and therefore, the first supply sold would lapse its return policy in 2016. This belies any contention that management properly estimated returns based on historical return history in a reasonable manner. Insys should have recorded a liability for the maximum potential amount of the refund or rebate in accordance with GAAP.

245. Management’s procedures regarding revenue also should have included examination to determine whether, pervasive evidence of an arrangement exists, delivery has occurred or services have been rendered, seller’s price to the buyer is fixed or determinable, and collectability is reasonably assured. Specifically, management should have reviewed all distributor contracts to ensure revenue is recognized appropriately. The review of contracts would determine if the arrangement exists and had a fixed price.

246. Additionally, management should have, but did not, review all large or unusual sales and corresponding credits. This examination would likely determine if customers had varying rights of returns, therefore, making the sale non-binding due to the lack of collectability and determinable price. Management also should have evaluated the distributor’s creditworthiness. If the creditworthiness of a customer is in doubt, then the collectability is not assured and the revenue should not be recognized. Indeed, as the 2016 Annual Report disclosed: “from time to time, late in a fiscal quarter, [we] offered to certain customers extended payment terms primarily in effect to increase customer orders during that quarter, which may have impacted sales in subsequent quarterly periods.”

## II. Insys Materially Misstated Rebates, Returns, and Sales Allowances

247. Accrued sales allowances, such as rebates, are a contra revenue account which reduces the amounts reported in a company's revenue. Rebates and returns are recorded in the same period that the related revenue is recognized resulting in a reduction of product sales revenue and the establishment of either a contra asset or a liability, which are included in accounts receivable or other accrued liabilities, respectively.

248. As a company's revenue increases the balance in the accrued sales allowance account should increase by a similar percentage. Compared to competitors, including Depomed, Inc. (a maker of drugs including a fentanyl spray), Insys had a marginal accrued sales allowance balance compared to gross sales. Indeed, even as the turmoil with Insys became increasingly public, the percentage of accrued sales allowance remained constant:

(in thousands unless otherwise stated)	<b>Insys -- As Restated</b>			
	<b>2016</b>	<b>2015</b>	<b>2014</b>	<b>2013</b>
Net Revenue	\$242,275	\$330,323	\$219,062	\$99,289
Provision for Discounts, Rebates & Returns	\$137,000	\$126,600	\$63,700	\$19,100
Gross Revenue	\$379,275	\$456,923	\$282,792	\$118,389
Accrued Sales Allowance	\$28,955	\$35,033	\$14,329	\$5,340
% of Accrued Sales Allowance/ Revenue	7.6%	7.7%	5.1%	4.5%

(in thousands unless otherwise stated)	<b>Depomed</b>			
	<b>2016</b>	<b>2015</b>	<b>2014</b>	<b>2013</b>
Net Revenue	\$455,066	\$341,750	\$114,219	\$58,302
Provision for Discounts, Rebates & Returns	\$323	\$206	\$70	\$27
Gross Revenue	\$455,389	\$341,956	\$114,289	\$38,329

Accrued Sales Allowance	\$131,536	\$121,058	\$35,710	\$19,496
% of Accrued Sales Allowance/ Revenue	28.9%	35.4%	31.2%	33.4%

249. ASC 605 provides guidance on how entities should account for sales of products when the buyer has a return privilege. ASC 605-15-21-1 specifies criteria for recognizing revenue when a right of return exists:

If an entity sells its product but gives the buyer the right to return the product, revenue from the sales transaction shall be recognized at time of sale only if all of the following conditions are met:

- a) the seller's price to the buyer is substantially fixed or determinable at the date of sale
- b) the buyer has paid the seller, or the buyer is obligated to pay the seller and the obligation is not contingent on resale of the product
- c) the buyer's obligation to the seller would not be changed in the event of theft or physical destruction or damage of the product
- d) the buyer acquiring the product for resale has economic substance apart from that provided by the seller
- e) the seller does not have significant obligations for future performance to directly bring about resale of the product by the buyer
- f) the amount of future returns can be reasonably estimated.

250. Further, under ASC 605-15-25-1(f) an entity must be able to make a reasonable estimate regarding future returns to recognize revenue upon shipment of the product. ASC 605-15-25-3 indicates that the ability to make such an estimate depends on many factors and notes that the following factors may impair this ability:

- a) The susceptibility of the product to significant external factors, such as technological obsolescence or changes in demand
- b) Relatively long periods in which a particular product may be returned
- c) Absence of historical experience with similar types of sales of similar products, or inability to apply such experience because of changing circumstances

d) Absence of a large volume of relatively homogeneous transactions

251. Thus, not only did this financial manipulation violate the Company's internal policies, which Defendants admit was the result of a reckless "tone at the top" amongst management, but it also resulted in a misapplication of the accounting guidance for revenue recognition (ASC No. 605, "Revenue Recognition") related to accounting for rebate obligations on government payer and managed care contracts, and further violated the U.S. GAAP as set out by the Financial Accounting Standards Board.

### **III. Insys Materially Misstated Stock Option Awards and Accrued Litigation.**

252. Insys reversed two out-of-period adjustments related to a stock option modification and the deductible interest portion of an accrued litigation award. The Statement of Financial Accounting Concepts No. 6, Elements of Financial Statements, explains the Matching Principle in which revenues and expenses that are directly related to each other are required to be recognized at the same time. Both adjustments were made to recognize expenses in the correct prior period which has a direct effect on revenue.

253. ASC 718-10-25-22 explains that a liability for the employer's portion of payroll taxes on employee stock compensation should be recognized on the date of the event triggering the obligation to pay the tax to the taxing authority. Even though the employer's payroll taxes are directly related to the appreciation of stock options, those taxes are part of the company's operating expenses and should be reflected as such in the company's income statement.

254. Insys failed to recognize the \$1.5 million operating expense during the three months ended December 31, 2015 and instead pushed the expenses to the subsequent three months ended March 31, 2016. By not abiding by the matching principal, failing to record the expense in the proper period, Insys inflated the revenue for the period ended December 31, 2015.

### **INSYS'S INTERNAL CONTROL VIOLATIONS**

255. During the Class Period, Defendants falsely represented that Insys maintained internal controls over financial reporting to ensure the reliability of the Company's financial reporting. In addition, during the Class Period, Defendants concealed a chronic and systematic breakdown of the Company's internal accounting controls, thereby allowing the Company to, among other things, artificially boost its revenue metrics and inflate the Company's stock price.

256. Defendants would eventually admit that the Company lacked internal controls beginning in the 2015 Annual Report stating Insys lacked adequate internal controls regarding its "accounting for stock option awards," but failed to disclose the Company's inadequate controls over financial reporting relating to sales rebates and returns. Indeed, investors did not learn about the Company's inadequate controls over financial reporting relating to sales rebates and returns until Defendants announced in March 2017 they had falsified and would be restating no less than three years of financial statements over six separate quarters.

257. As a result of Defendants' failure to maintain effective internal controls, they were able to artificially boost the Company's faltering revenue metrics by deliberately or recklessly understating its rebate obligations to, and product returns by, third-party payers.

258. As the SEC has explained, internal controls are fundamental and critical for summarizing and reporting financial data . . . ." 15 U.S.C. § 78m(b)(2).<sup>17</sup> Indeed, a lack of fundamental internal controls, as here, constitutes a "***material*** weakness" that should be immediately disclosed to investors under GAAP.

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<sup>17</sup> Specifically, the SEC requires a public company to: (a) make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of assets of the issuer; and (b) devise and maintain a system of internal accounting controls . . . ." 15 U.S.C. § 78m(b)(2).

259. Generally accepted auditing standards (“GAAS”) set forth the role of a Company’s management in an audit of an entity’s financial statements. Specifically:

[M]anagement and, when appropriate, those charged with governance, have responsibility

a. for the preparation and fair presentation of the financial statements in accordance with the applicable financial reporting framework;

b. for the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error...<sup>18</sup>

260. The Individual Defendants were further required under Rule 302 of the Sarbanes-Oxley Act of 2002 to provide certifications relating to the company’s internal controls over financial reporting in the False and Misleading Financial Statements.

261. Additionally, Section 302 of the Sarbanes-Oxley Act of 2002 required Defendants to maintain, assess and report on the effectiveness of the Company’s internal control over financial reporting. The language provides the following, in relevant part:

(a) REGULATIONS REQUIRED.—The Commission shall, by rule, require, for each company filing periodic reports under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m, 78o(d)), that the principal executive officer or officers and the principal financial officer or officers, or persons performing similar functions, certify in each annual or quarterly report filed or submitted under either such section of such Act that—

(1) the signing officer has reviewed the report;

(2) based on the officer’s knowledge, the report does not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which such statements were made, not misleading;

(3) based on such officer’s knowledge, the financial statements, and other financial information included in the report, fairly present in all material respects the financial condition and results of operations of the issuer as of, and for, the periods presented in the report;

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<sup>18</sup> AU-C Preface – *Principles Underlying an Audit Conducted in Accordance with Generally Accepted Auditing Standards*.

(4) the signing officers—

- (A) are responsible for establishing and maintaining internal controls;
- (B) have designed such internal controls to ensure that material information relating to the issuer and its consolidated subsidiaries is made known to such officers by others within those entities, particularly during the period in which the periodic reports are being prepared;
- (C) have evaluated the effectiveness of the issuer's internal controls as of a date within 90 days prior to the report; and
- (D) have presented in the report their conclusions about the effectiveness of their internal controls based on their evaluation as of that date . . .

262. Auditing standards established and adopted by the Public Company Accounting Oversight Board (the “PCAOB”), specifically Auditing Standard (“AS”) No. 5, An Audit of Internal Control over Financial Reporting that is Integrated with an Audit of Financial Statements and Related Independence Rules and Conforming Amendments (“AS 5”), defines internal controls over financial reporting as follows:

Internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP and includes those policies and procedures that –

- (1) Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;
- (2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- (3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.<sup>19</sup>

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<sup>19</sup> AS 5, Appendix A, A-5.

263. Professional accounting standards recognize that a company's control environment sets the tone of an organization, and is the foundation for all other components of internal control, providing discipline and structure. The Committee of Sponsoring Organizations of the Treadway Commission framework also discusses a Company's control environment as being one of five interrelated components of internal control, stating:

Control environment. Senior management must set an appropriate "tone at the top" that positively influences the control consciousness of entity personnel. The control environment is the foundation for all other components of internal control and provides discipline and structure.

264. The Company's most senior executive management, consisting in substantial part of the Individual Defendants herein, embraced an admitted "tone at the top" of prematurely recording revenue and failing to properly account for product returns and rebates, thereby overstating revenue and earnings. The purported control environment created by the Individual Defendants allowed for the concealment of material information concerning the Company's core business (Subsys) in order keep the Company's stock price artificially inflated throughout the Class Period.

265. Moreover, Defendants' failure to identify such control deficiencies (*e.g.*, material weaknesses) within the Company rendered Defendants' Sarbanes Oxley reports in the False and Misleading Statements section materially false and misleading in turn, and contributed to the Company's issuance of materially false and misleading financial statements in violation of GAAS.

#### **ADDITIONAL SCIENTER ALLEGATIONS**

266. As alleged herein, each of the Individual Defendants acted with scienter in that they knew or recklessly disregarded that the public statements and documents issued and disseminated in the name of the Company were materially false and misleading, knew or acted with deliberate recklessness in disregarding that such statements and documents would be issued and disseminated

to the investing public, and knowingly and substantially participated and/or acquiesced in the issuance or dissemination of such statements and documents as primary violators of the federal securities laws.

267. The Individual Defendants had the opportunity to commit and participate in the wrongful conduct complained of herein. Each was a senior executive officer and/or director of Insys and, thus, controlled the information disseminated to the investing public in the Company's press releases and SEC filings. As a result, each could falsify the information that reached the public about the Company's business and performance.

268. Throughout the Class Period, each of the Individual Defendants acted intentionally or recklessly and participated in and orchestrated the fraudulent schemes alleged herein to conceal the true nature and extent of the Company's business, operations, growth, financial statements, and financial condition. Such actions allowed Insys to artificially inflate net revenue and the Company's stock price. The Individual Defendants' scienter may be imputed to Insys as the Individual Defendants were among Insys's most senior management and were acting within the scope of their employment.

#### **I. The Individual Defendants Knowingly and Recklessly Misrepresented Insys's Financial Statements**

269. Prior to and throughout the Class Period, the Individual Defendants knew that the Company had improperly understated its rebate obligations to third-party payers, product returns by distributors, and in turn, understated its provisions for sales allowance to boost the Company's faltering revenue in the face of increased regulatory scrutiny and reluctance by third-party payers to subscribe and/reimburse Subsys prescriptions, as evidenced by: (A) Defendants' own admission that the false financial statements and subsequent restatement was the result of an inadequate "tone at the top" amongst Insys management; (B) Defendants admittedly monitored Subsys prescriptions

and reimbursement rates which would have altered them to Insys's improper accounting and GAAP violations; (C) Defendants were admittedly in constant communications with third-party payers, which also would have demonstrated to them Insys's improper accounting and GAAP violations; (D) Defendants violated the Company's own internal accounting policies; (E) the sale of Subsys and reimbursement by third-party payers is Insys's "core" business; and (F) the curiously timed terminations or resignations of the Company's Chief Operating Officer, Chief Executive Officer, Interim Chief Executive Officer, Chief Medical Officer, and Chief Financial Officer (*i.e.* the entire executive management team) over the course of only nine months.

**A. Defendants Admit the Restatement Was "Material" and the Result of an Inadequate "Tone at the Top."**

270. The Individual Defendants eventually admitted that Insys lacked the necessary internal controls for accurate financial reporting, particularly as the controls related to rebates and returns, for at least the 2015 and 2016 fiscal year. The Individual Defendants further admitted that the lack of internal controls was the result of an inadequate "*tone at the top*" amongst management, and that this tone at the top had resulted in "material" errors with respect to accounting for the rebates component of our product sales allowances and the allowance for excess and obsolete inventory matters.

271. Defendants' admissions in the 2016 Annual Report is further corroborated by the fact that the Audit Committee conducted an investigation and independent review of the Company's processes related to estimation of, and increases to, certain sales allowances recorded during 2016, and engaged both independent legal counsel and a forensic accounting firm to assist its investigation.

272. Accordingly, although Insys touted its Subsys revenue and reimbursement relationships with third-party payers as "critical" to Insys's sustained viability – these figures, as

reflected in the Company's sales allowance and net revenue, were falsely reported and the Company lacked the necessary internal controls to appropriately assess and estimate either metric. Thus, throughout the Class Period, Defendants continually assured investors that Insys's internal controls were "effective" and/or that the Company actively complied with GAAP, with no reasonable basis for making such statements.

273. The Company's determination and subsequent public admission that its own management "did not display an adequate tone at the top with respect to judgment and rigor," which resulted in in "material" errors with respect to the reporting of the Company's purportedly "critical" financial metrics, coupled with the "resignation" of the Company's CFO, Defendant Baker, soon thereafter, is therefore extraordinary evidence of scienter.

**B. Defendants Admitted to Actively Monitoring Subsys Prescriptions and Reimbursement Rates, Which Would Have Alerted Them to Insys's Improper Accounting and GAAP Violations.**

274. Defendants stated repeatedly, including in every quarterly and annual report that the Company filed during the Class Period, that the Individual Defendants actively surveyed the rate of Subsys subscriptions in any given quarter using real-time data from the TIRF-REMS Access Program. In particular, as a mandated participant in the TIRF-REMS Access Program, Insys received quarterly reports on the prescription and usage of TIRF medicines and had daily access to the number of Subsys prescriptions being written in real-time.

275. As Defendant Kapoor explained: "*we [including defendant Kapoor] have a meeting every day at 8:30 in the morning looking at what happened yesterday. I can tell you how many scripts we did yesterday. And we do that every single day, because Subsys is so important to us.*"

276. Thus, in accordance with Insys's own internal practices and policies, the Individual Defendants were able to, and did, monitor and analyze the prescriptions written by every TIRF-

REMS enrolled prescriber, the usage of every TIRF-REMS enrolled patient, and the number of Subsys prescriptions being written on a daily basis, real-time. Accordingly, Defendants admittedly knew that doctors were refusing to write Subsys prescriptions as a result of increased regulatory scrutiny and third-party payers were refusing to reimburse off-label Subsys prescriptions, and distributors were also returning unused, expired Subsys orders. As such, Defendants also knew or should have known that the Company's financial statements had falsely understated its rebate obligations to third-party payers, product returns by distributors, and in turn, understated its provisions for sales allowance.

**C. Defendants Were Admittedly in Constant Communications with Third-Party Payers Which Would Have Alerted Them to Insys's Improper Accounting and GAAP Violations.**

277. The Individual Defendants' knowledge is further evident by the fact that they were holding discussions directly with third-party payers regarding Subsys reimbursement throughout the Class Period, and in particular, the growing reluctance by third-party payers to reimburse Subsys prescriptions as the Company's illicit off-label marketing and kickback scheme was publicly revealed and multiple high-level Subsys employees and executives were fired, arrested, and indicted.

278. Throughout the Class Period, the Individual Defendants directed, encouraged, and monitored the efforts to increase doctors' prescriptions and ensure authorization by third-party payers.

279. The pressure to sell Subsys for off-label use came from the top of the Insys organization—the Individual Defendants. For example, in an October 2013 email, quoted in the Massachusetts indictment, Insys's former Vice President of Sales castigated a sales representative about a physician's failure to write as many Subsys prescriptions as the Company had hoped for:

“Where is [the prescribing physician]?

Not even close to meeting anyone's expectations thus far, perhaps – We had failed in setting our expectations?

We were looking to go from 40 percent market share to 90 percent? . . . I ***have to sit in the corporate office and answer these questions face to face.*** It is not fun, and the recent move we made on an ABL appears as if it is potentially not worth it?"

280. This pressure persisted before and during the Class Period. As for Insys's efforts to achieve high levels of authorizations from third-party payers, the Senate Governmental Affairs Committee report found that IRC "employees reportedly received significant financial incentives and management pressure—including quotas and group and individual bonuses—to boost the rate of Subsys authorizations." A former Insys employee reported that the leader of the IRC "personally pressured IRC employees to improve the rate of prescription approvals, noting that [Individual Defendant] 'Dr. Kapoor's not happy, we have to get these approvals up.'"

281. According to a criminal indictment filed by the Massachusetts Attorney General and a civil complaint filed by the New Jersey Attorney General, these financial bonuses to IRC members for achieving certain numbers of prior authorizations continued through the Class Period, well after myriad improprieties concerning Insys's sales practices had already been revealed.<sup>20</sup>

282. During the Class Period, individuals at the highest levels of the Company ensured high volumes of prescriptions by giving sales representatives substantial bonuses. According to the New Jersey Complaint,

"As recently as June 2016, in response to the consulting firm's findings, Insys Executive Vice President and former COO Daniel Brennan ("Brennan") emailed Kapoor to relay his serious concerns about Insys's "overall sales rep compensation" structure, as well as Insys's hiring of subpar pharmaceutical representatives. In particular, Brennan explained that Insys is "still creating an environment of non-compliance by paying a low base salary (barely above minimum wage) and then very high ratio of incentive pay as their overall comp."

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<sup>20</sup> Indictment, *USA v. Babich*, No. 1:16-cr-10343-ADB (D. Mass. filed Dec. 6, 2016) at ¶¶ 9, 65, 114 (the "Massachusetts Indictment"); Complaint, *Attorney General of N.J. v. Insys Therapeutics, Inc.*, No. A 8:54 (filed Oct. 5, 2017) ("NJ Complaint" or "NJ Compl.") ¶¶ 184-86.

Indeed, as Brennan explained to Kapoor, the consulting firm's interviews of Insys's employees revealed that they themselves found that Insys's "compensation structure encouraged inappropriate behavior," which Brennan assumed to mean "off label promotion and quid pro quo behavior." In Brennan's words, "with a potent pain product like [Subsys] ha[s], it is dangerous to have so little previous pharma experience/training." Brennan "strongly recommended" a change in payment structure "that is more in line with industry standards and creates a more compliant-behaving sales organization (important given the scrutiny we have with DOJ and media coverage of our company —both affecting our reputation and trust with customers and our internal personnel)."

After Kapoor forwarded Brennan's email to Insys Board Member Patrick Fourteau, Fourteau replied to Brennan by stating that he did "not like either the tone or the substance of [Brennan's] message."

When Kapoor responded to Brennan's email the following day, he, among other things, attempted to shift the blame from Insys to Brennan: "To be entirely honest, I am a little concerned that your email directly follows on the heels of the recent termination discussions (and actions) related to your commercial team."<sup>21</sup>

283. Senior leadership at Insys, including Individual Defendant Babich, personally approved the details of the company's scheme to obtain third party payers' approval for off-label use of Subsys. According to a qui tam complaint filed in federal court in Texas, former Insys sales representative Ray Furchak "personally witnessed" that Babich "participated in the nationwide off-label marketing scheme or knew of it yet did nothing to limit it."<sup>22</sup>

284. The Company's IRC, at the direction of the Individual Defendants, interacted directly with third-party payers in an attempt to obtain authorizations and insurance coverage for Subsys and, thus, knew that these payers were refusing to reimburse off-label Subsys prescriptions that the Company had fraudulently secured from doctors through its widespread kickback scheme.

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<sup>21</sup> NJ Compl. ¶¶ 124-127.

<sup>22</sup> *USA ex rel. Furchak v. Insys Therapeutics, Inc.*, No. 4:12-cv-02930 (S.D. Tex. Filed Sept. 28, 2012).

285. For example, as Insys learned that insurers and PBMs were denying authorizations unrelated to breakthrough cancer pain, they investigated other off-label uses. The Defendants discovered that third-party payers were sometimes willing to grant prior authorization when a patient was diagnosed with dysphagia, or difficulty swallowing. Senior leadership at the Company then approved a “model letter of medical necessity” for physicians attesting to their patients’ dysphagia—whether they had dysphagia or not. According to the Massachusetts indictment:

***“At a Company leadership meeting, [Individual Defendant] BABICH, GURRY, AND [former Insys VP of Sales] BURLAKOFF were presented the dysphagia diagnosis [a form letter] and the procedures the Reimbursement Unit used to gain prior authorization from insurers and pharmacy benefit managers using the dysphagia diagnosis.”***

286. In addition, according to the Massachusetts indictment, the IRC used false cancer diagnoses and false statements concerning alternative medications, to obtain authorization.

287. Indeed, Defendants admitted their direct involvement in the IRC’s interaction with third-party payers. For example, in a February 23, 2017 conference call, Defendant Baker stated “we continue to engage in dialogue with payers, as we continue to educate them on the benefits of these medications, [] that pressure will start to subside” and “our strategy will be to continue to price in the range with the class, and continue to dialogue with payers on why they should be reimbursing TIRF products.”

288. Insys’s direct interactions with third-party payers, through the IRC and otherwise, indicate that the Individual Defendants not only had undisclosed inside knowledge that their conduct provided a basis for third-party payers to refuse to reimburse Subsys prescriptions, but also that the third-party payers in fact were refusing to do so. Moreover, Defendants’ knowledge of the risk of future product returns is also reflected in the fact that the Company sought to negotiate

with these payers regarding their reimbursement practices in an attempt to salvage the Company's faltering revenues.

**D. Defendants Admittedly Violated Their Own Internal Policies and Procedures With Respect to Revenue Recognition.**

289. The Individual Defendants' knowledge and/or severe recklessness is also evidenced by their admitted violations of their own internal policies and procedures with respect to revenue recognition. Although Insys's revenue recognition policy stated that "revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured," Insys did not comply with the policy because the price was not fixed or determinable due to distributor's lengthy rights of return.

290. Further, although Defendants represented throughout the Class Period that they "have monitored actual return history since product launch, which provides us with a basis to reasonably estimate future product returns, taking into consideration the shelf life of product at the time of shipment, shipment and prescription trends, estimated distribution channel inventory levels, and consideration of the introduction of competitive products," the 36-month Subsys shelf life meant the first supply sold would lapse its return policy in 2016 thus belying any reasonable contention that management could properly estimate returns based on historical return history in a reasonable manner for a period that didn't lapse until last year.

291. As Defendants have since admitted, they did not comply with the Company's own internal policies and procedures with respect to revenue recognition, led by an inadequate "tone at the top with respect to judgment and rigor," which resulted in in "material" errors with respect to the reporting of the Company's purportedly "critical" financial metrics. Their failure to follow their own policies and procedures further supports a finding of their knowledge or recklessness.

**E. The Sale of Subsys, and Coverage and Reimbursement by Third-Party Payers, Is Insys's "Core Business."**

292. During the Class Period, the Individual Defendants were Insys's most senior executives with direct control and supervision over its business, operations, and public statements. By virtue of their executive positions and hands-on management styles, the Individual Defendants knew non-public material facts concerning Subsys, which is Insys's core business, and accounted for more than 98% of the Company's revenues during the Class Period. As the Company has repeatedly stated: “[w]e are largely dependent on the commercial success of our product, SUBSYS®...our ability to maintain profitability will depend upon the continued commercial success of our main approved product, SUBSYS®,” and “[o]ur sales of, and revenue from, Subsys depended in significant part on the coverage and reimbursement policies of third-party payers.”

293. The Company's net revenues, profit margins, and sustainability depended almost entirely upon sales of Subsys and was in fact so important to the Company throughout the Class Period that the Individual Defendants monitored Subsys sales every single day, as detailed *supra*. Given that Subsys was Insys's only drug product on the market and the Company's financial viability depended on the success of Subsys, during the Class Period. Subsys constituted the Company's core business operations and a vital corporate function that Subsys's most senior executives are rightly presumed to have knowledge of as a matter of law. Accordingly, the Individual Defendants knew or were deliberately reckless in not knowing that the Company had improperly understated its rebate obligations to third-party payers, product returns by distributors, and in turn, understated its provisions for sales allowance to boost the Company's faltering revenue metrics.

**F. The Curiously Timed Resignations or Terminations of the Company’s Chief Operating Officer, Chief Executive Officer, Interim Chief Executive Officer, Chief Medical Officer, and Chief Financial Officer Support an Inference of Scienter.**

294. The terminations or resignations of the Company’s Chief Operating Officer, Chief Executive Officer, Interim Chief Executive Officer, Chief Medical Officer, and Chief Financial Officer (*i.e.* the entire executive management team) over the course of only nine months as the Company struggled to conceal the true extent of third-party payer pressure and returns, and investors began to learn the truth regarding their fraudulent financial manipulations, further give rise to a strong inference of scienter. For example, on August 10, 2016, only seven days after Insys announced a 13.1% decrease in total net revenue for the second quarter 2016, the Company announced that the employment of then-Insys Executive Vice President and Chief Operating Officer Brennan had been inexplicably “terminated.” Brennan had just recently joined Insys in November 2015 to rehabilitate its compliance department and thus, his abrupt termination came only nine months after his initial appointment.

295. Roughly one month after Brennan’s termination, on September 21, 2016, Insys announced that the Company’s Board had initiated a search to identify a new CEO to replace then-CEO Kapoor. Kapoor had assumed the position only one year prior, following the resignation and subsequent arrest and criminal indictment of the Company’s former CEO, Babich. Although the September 2016 Press Release assured investors that Kapoor would continue as CEO until a replacement had been appointed, on January 9, 2017, Insys announced he had abruptly retired, effective the same date, before the Board identified a replacement CEO. Kapoor’s purported retirement came amid growing public revelation regarding Insys’s longstanding illicit kickback scheme to promote Subsys for prescription by paying doctors illegal remunerations.

296. Kapoor was succeeded the same day by Vetticaden, who was appointed Interim CEO on January 9, 2017. Only three months after initial his appointment, however, and only seven business days after the Company's March 31, 2017 announcement that its previously issued financial statements should no longer be relied upon, Insys announced on April 11, 2017 that it had "accepted" the resignation of Vetticaden as both Interim CEO and Chief Medical Officer. Only one month after Vetticaden's purported resignation, Insys announced on May 16, 2017 that Baker would "transition" out of the role of CFO. Prior to his termination, Baker had been the CFO of Insys since October 2012 and according to the Company, had "extensive experience in accounting, SEC compliance for smaller public companies, merger and acquisition transactions, and small business financing."

297. The sudden, unexplained, and suspicious mass exodus of the Company's entire executive management team provides strong additional support that they and the Defendants knew of the Company's pervasive fraud during their tenure with the Company.

## **II. The Individual Defendants' Motive to Misrepresent Insys's Financial Statements**

298. The Individual Defendants were motivated to engage in the alleged fraudulent scheme and issue materially false and misleading statements and/or omit material facts in order to: (i) stabilize the Company's financials in the face of growing regulatory and criminal scrutiny; (ii) perpetuate the well-documented corporate culture at Insys of placing revenues above all else; and (iii) engage in insider trading.

### **A. The Defendants Were Motivated to Perpetuate the Alleged Scheme to Stabilize the Company's Financials in the Face of Growing Controversy.**

299. As was slowly being revealed to the market beginning in September 2014 when Insys received a subpoena from the U.S. Attorney's office for the District of Massachusetts, and culminating in the arrest and indictment of former Insys CEO Babich and former Vice President

of Sales Burlakoff in December 2016 for violations of the RICO Act, Subsys's unprecedented revenue growth since its launch in January 2012 was actually the byproduct of persistent illegal off-label marketing, illegal kickbacks to prescribers, and a wide-ranging scheme to defraud third-party payers into authorizing insurance coverage for off-label prescriptions of Subsys by misrepresenting the health conditions of the persons to whom Subsys was prescribed.

300. Accordingly, in the face of these pressures, the Individual Defendants were motivated to improperly overstate Insys revenue and earnings and understate Insys's rebate obligations to third-party payers, product returns by distributors, and in turn, understate its provisions for sales allowance, to perpetuate an illusion of continued financial health in the face of continued pressure by third-party payers.

**B. The Defendants Were Motivated to Perpetuate the Alleged Scheme Due to the Well-Documented Corporate Culture at Insys of Placing Revenues Above All Else.**

301. Relatedly, the Individual Defendants' motivations to improperly understate Insys's rebate and return obligations and thus, deceive investors, is further supported by the culture the Individual Defendants themselves fostered within Insys – one that established the sale of Subsys and the growth in the Company's share price as the sole and overriding objective of all employees, no matter what steps were required to achieve that end, even at the expense of patient health and criminal activity. As is well documented in the December 2016 criminal indictment of former CEO Babich and former Vice President of Sales Burlakoff, as well as numerous other civil and criminal actions such as the Illinois Complaint, the Individual Defendants established and perpetuated a corporate environment at Insys that was scarred by chronic civil and criminal misconduct driven by a relentless hunger for revenue.

302. Accordingly, it should come as no surprise that the Company also manipulated its accounting practices in order to maximize revenue. Indeed, throughout the Class Period, the

Company violated basic, long-standing principles of GAAP related to revenue recognition and its own internal policies related to accounting for rebates and sales allowance. These are accounting errors and GAAP violations that, contrary to the Defendants' numerous public statements that it maintained effective internal controls and reported in compliance with GAAP, would also belie the Defendants' proven capabilities absent fraud.

**C. The Insider Trading by Insys Insiders Intimately Involved With the Accounting Fraud Investigation and Restatements Supports an Inference of Scienter.**

303. The Individual Defendants were motivated to engage in the alleged fraudulent scheme and issue materially false and misleading statements and/or omit material facts in order to inflate Insys's common stock price and maximize their individual profits through insider trading. As reflected in the chart below, Insys insiders collectively sold 188,940 shares of Insys common stock over the course of the Class Period for collective proceeds of approximately \$6,285,580:

Date	Insider	Shares Sold	Proceeds	10b5-1 Plan
8/16/2016	Director (Theodore Stanley)	15,000	\$270,300	No
8/11/2016	Director (Patrick Fourteau)	15,000	\$276,900	No
8/9/2016	Exec VP & COO (Daniel Brennan)	5,781	\$110,752	No
6/6/2016	Director (Theodore Stanley)	16,000	\$260,320	No
3/4/2016	Director (Theodore Stanley)	20,000	\$362,200	No
3/4/2016	Director (Patrick Fourteau)	15,000	\$273,300	No
11/12/2015	Director (Patrick Fourteau)	30,000	\$794,400	No
9/10/2015	Director (Theodore Stanley)	4,000	\$148,167	No
6/10/2015	General Counsel (Franc Del Fosse)	10,000	\$344,800	No
6/5/2015	Director (Steven Meyer)	5,000	\$315,000	No

5/26/2015	Director (Brian Tambi)	4,900	\$294,279	No
5/26/2015	Director (Patrick Fourteau)	6,095	\$365,884	No
5/19/2015	Director (Patrick Fourteau)	9,064	\$543,840	No
5/19/2015	Director (Brian Tambi)	5,100	\$306,558	No
5/18/2015	CFO (Darryl S Baker)	10,000	\$591,720	Yes
5/11/2015	Director (Steven Meyer)	18,000	\$1,027,160	No
<b>TOTAL</b>		<b>188,940</b>	<b>\$6,285,580</b>	

304. As the foregoing chart reflects, insiders at Insys engaged in suspicious trading activity during the Class Period. For example, del Fosse, the Company's General Counsel since February 2014, reduced his shareholdings by 100 percent during the Class Period. Mr. del Fosse did not trade pursuant to a Rule 10b5-1 trading plan.

305. In addition, Director Theodore H. Stanley, M.D., a member of the Company's Compensation Committee and the Nominating and Corporate Governance Committee,<sup>23</sup> sold no shares before the Class Period, but sold 55,000 shares during the Class Period (through the exercise and sale of stock options), for proceeds of \$1.04 million and profits of \$806,400. Stanley's trades were not made pursuant to a Rule 10b5-1 trading plan.

306. Furthermore, Director Fourteau sold 75,159 shares during the Class Period, causing his total shareholdings to decline by 29 percent.<sup>24</sup> He received proceeds of \$2,254,000. Fourteau did not trade pursuant to a Rule 10b5-1 trading plan.

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<sup>23</sup> See <[http://investors.insysrx.com/phoenix.zhtml?c=115949&p=irol-govcommcomp\\_pf](http://investors.insysrx.com/phoenix.zhtml?c=115949&p=irol-govcommcomp_pf)>.

<sup>24</sup> After accounting for the effect of the June 5, 2015, 1-for-2 stock split, Fourteau's shareholdings declined by 55%.

307. In addition, during the Class Period, Babich submitted Form 144 filings with the SEC that indicated his intent to sell 483,887 shares of Insys common stock, valued at \$14,039,100.00.

Date	Shares Sold	Proceeds
12/3/15	2,189	\$91,000
12/1/15	30,000	\$1,000,000
11/25/15	20,000	\$643,700
11/24/15	30,000	\$938,200
11/23/15	70,000	\$2,200,000
11/19/15	27,839	\$844,100
11/18/15	36,800	\$1,100,000
11/17/15	40,000	\$1,200,000
11/16/15	21,017	\$622,100
11/13/15	89,334	\$2,600,000
11/9/15	100,000	\$2,800,000
<b>TOTAL</b>		<b>\$14,039,100</b>

308. Furthermore, many large dispositions by other Insys insiders occurred on or closely around market moving news days were highly unusual in both timing and amount, and correlated with market moving events or dates on which the Individual Defendants were likely be in possession of material non-public information. Illustrative of this fact, on August 9, 2016 then-Executive Vice President and Chief Operating Officer of Insys, Brennan, sold 100% of his 5,781 outstanding shares of Insys common stock at \$19.18 per share for total proceeds of approximately \$110,752.00. The following day, on August 10, 2016, the Company disclosed that Brennan had been inexplicably “terminated.”

309. On this news, the Company's common stock declined from a closing price of \$19.38 per share on August 9 to close at \$18.54 per share on August 11, a decline of approximately 5 percent on heavy trading volume. As such, their insider sales are probative of scienter.

### **LOSS CAUSATION**

310. During the Class Period, Defendants materially misled the investing public about the Company's finances, operational and compliance policies, thereby inflating the price of Insys's common stock.

311. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, the Defendants named in this Action made or caused to be made a series of materially false and/or misleading statements about Insys, its finances, and operational and compliance policies. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its well-being and prospects, thus causing the Company's stock to be overvalued and artificially inflated at all relevant times.

312. The materially false and/or misleading statements made by the Defendants named in this Action during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's stock at artificially inflated prices, thus causing the damages complained of herein. For example:

- In reaction to the May 7, 2015 Press Release announcing Insys's first quarter 2015 financial results, including that total revenue increased to \$70.8 million versus \$41.6 million for the first quarter of 2014, the Company's stock price increased 8 percent from \$26.73 per share on May 6, 2015 to close at \$28.88 per share on May 11, 2015.
- In reaction to the November 5, 2015 Press Release announcing Insys's third quarter 2015 financial results, including total net revenue of \$91.3 million versus \$58.3

million for the third quarter of 2014, the Company's stock price increased 7.7 percent from \$25.43 per share on November 5, 2015 to close at \$27.39 per share on November 6, 2015.

- In reaction to the 2015 Annual Report, in which Insys announced total net revenue for the fourth quarter 2015 had increased to \$91.1 million, compared to \$66.5 million for the fourth quarter of 2014, the Company stock price increased 6.2 percent from \$26.21 per share on February 20, 2015 to close at \$27.83 per share on February 24, 2015.

313. During the Class Period, as detailed herein, the Defendants engaged in a scheme to deceive the market and perpetuate a course of conduct that caused the price of Insys common stock to be artificially inflated by failing to disclose and/or misrepresenting the adverse facts detailed herein. As the Defendants' misrepresentations and fraudulent conduct were disclosed and became apparent to the market, the artificial inflation in the price of Insys shares was removed, and the price of Insys shares fell.

314. For example, when, on March 15, 2017, Insys announced that the Audit Committee was investigating accounting manipulations relating to Insys' reported revenue and sales allowance causing the Company to delay the release of its financial results for the fourth quarter and full year 2016, the price of Insys common stock declined from a closing share price of \$10.55 on March 15, 2017 to \$10.05 at close on March 16, 2017, a loss of 4.64 percent, on heavy trading volume that was 37.4% higher than the prior day. In contrast, on March 16, 2017 the Nasdaq US Smart Pharma Index was up 1.6%.

315. As a result of their purchases of Insys securities during the Class Period at artificially inflated prices, Plaintiff, and the other Class members suffered economic loss, *i.e.*, damages, under the federal securities laws. The timing and magnitude of the price decline in Insys shares negate any inference that the loss suffered by Plaintiff and the other Class members was

caused by changed market conditions, macroeconomic or industry factors, or Company-specific facts unrelated to the Defendants' fraudulent conduct.

**CLASS ACTION ALLEGATIONS**

316. Plaintiff brings this action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3) on behalf of a class of all persons or entities that purchased or otherwise acquired Insys securities between May 7, 2015 and March 15, 2017, inclusive, seeking to pursue remedies under the Exchange Act.

317. Excluded from the Class are Insys and its subsidiaries and affiliates, and their respective officers and directors at all relevant times, and any of their immediate families, legal representatives, heirs, successors, or assigns, and any entity in which any Defendant has or had a controlling interest.

318. Because Insys had millions of shares outstanding during the Class Period, and because its shares were actively traded on the NASDAQ, the members of the Class are so numerous that joinder of all Class members is impracticable. While the exact number of Class members is unknown at this time and can only be ascertained through discovery, Plaintiff believes that there are, at a minimum, thousands of Class members. Members of the Class may be identified from records maintained by Insys or its transfer agent and may be notified of the pendency of this action by mail, using forms of notice customarily used in securities class actions.

319. Plaintiff's claims are typical of those of the members of the Class, as all Class members have been similarly affected by Defendants' wrongful conduct as alleged herein.

320. Plaintiff will fairly and adequately protect the interests of the Class and has retained counsel competent and experienced in class action and securities litigation.

321. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members. These common questions include:

- a. Whether Defendants violated the federal securities laws as alleged herein;
- b. Whether Defendants' statements to the investing public during the Class Period misrepresented material facts about Insys's business and operations;
- c. Whether the price of Insys shares was artificially inflated during the Class Period; and
- d. The extent to which members of the Class have sustained damages and the proper measure of damages.

322. A class action is superior to all other available methods for the fair and efficient adjudication of this matter as joinder of all Class members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for Class members to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

#### **NO STATUTORY SAFE HARBOR**

323. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Amended Class Action Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward- looking statements pleaded herein, Defendants are liable for those false forward-

looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Insys who knew that the statement was false when made.

**APPLICABILITY OF FRAUD ON THE MARKET DOCTRINE**

324. The market for Insys common stock was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Insys stock traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired the Company's stock relying upon the integrity of the market price of Insys and market information relating to the Company, and have been damaged thereby.

325. During the Class Period, the artificial inflation of Insys stock was caused by the material misrepresentations and/or omissions particularized in this Amended Complaint causing the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, the Defendants named in this Action made or caused to be made a series of materially false and/or misleading statements about the Company's finances, operational and compliance policies. These material misstatements and/or omissions created an unrealistically positive assessment of Insys and its business, operations, and prospects, thus causing the price of the Company's stock to be artificially inflated at all relevant times.

326. When the truth was revealed, it negatively affected the value of the Company shares. The Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's stock at such artificially inflated prices, and each of them has been damaged as a result.

327. At all relevant times, the market for Insys common stock was an efficient market for the following reasons:

- a. Insys common stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;
- b. As a regulated issuer, Insys filed periodic public reports with the SEC and the NASDAQ;
- c. Insys communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;
- d. During the class period, on average, over several hundreds of thousands of shares of Insys stock were traded on a weekly basis. On news days, the Company's trading volume increased into the millions, reflecting an active trading market for Insys common stock and investors' expectations being impounded into the stock price; and
- e. The proportion of statistically significant stock price movement days for Insys common stock on news days is significantly over the proportion of non-news days and, thus, Insys common stock is more likely to have a statistically significant return on a day with news than no-news, consistent with an informationally efficient market.

### COUNT I

#### **For Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Against Insys and the Individual Defendants**

328. Plaintiff realleges each allegation as if fully set forth herein.

329. This claim is brought under §10(b) of the Exchange Act, 15 U.S.C. § 78j(b) and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.

330. Defendants: (a) employed devices, schemes and artifices to defraud; (b) made untrue statements of material fact and/or omitted material facts necessary to make the statements made not misleading; and (c) engaged in acts, practices and a course of business which operated as a fraud and deceit upon Plaintiff and the Class, in violation of §10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

331. Defendants individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or the mails, engaged and participated in a continuous course of conduct to conceal non-public, adverse material information about the Company's outlook and condition, as reflected in the misrepresentations and omissions set forth above.

332. The Individual Defendants each had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth by failing to ascertain and to disclose such facts even though such facts were available to them, or deliberately refrained from taking steps necessary to discover whether the material facts were false or misleading.

333. As a result of Defendants' dissemination of materially false and misleading information and their failure to disclose material facts, Plaintiff and the Class were misled into believing that the Company's statements and other disclosures were true, accurate, and complete.

334. Insys is liable for the acts of the Individual Defendants and other Company personnel referenced herein under the doctrine of respondeat superior, as those persons were acting as the officers, directors, and/or agents of Insys in taking the actions alleged herein.

335. Plaintiff and the Class purchased Insys securities, without knowing that Defendants had misstated or omitted material facts about the Company's performance or prospects. In so doing, Plaintiff and the Class relied directly or indirectly on false and misleading statements made by the Count I Defendants, and/or an absence of material adverse information that was known to the Count I Defendants or recklessly disregarded by them but not disclosed in Defendants' public statements. Plaintiff and the Class were damaged as a result of their reliance on Defendants' false statements and misrepresentations and omissions of material facts.

336. At the time of Defendants' false statements, misrepresentations and omissions, Plaintiff and the Class were unaware of their falsity and believed them to be true. Plaintiff and the Class would not otherwise have purchased Insys stock had they known the truth about the matters discussed above.

337. By virtue of the foregoing, Defendants have violated §10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

338. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the Class have suffered damages in connection with their purchase of Insys securities.

339. This action was filed within two years of discovery of the fraud and within five years of Plaintiff's purchases of securities giving rise to the cause of action.

## **COUNT II**

### **For Violations of Section 20(a) of the Exchange Act Against the Individual Defendants**

340. Plaintiff realleges each allegation as if fully set forth herein.

341. This claim is brought under §20(a) of the Exchange Act, 15 U.S.C. § 78t, against the Individual Defendants as control persons.

342. Each of the Individual Defendants, by reason of their status as senior executive officers and/or directors of Insys, directly or indirectly, controlled the conduct of the Company's business and its representations to Plaintiff and the Class, within the meaning of §20(a) of the Exchange Act. The Individual Defendants directly or indirectly controlled the content of the Company's SEC statements and press releases related to Plaintiff's and the Class' investments in Insys securities within the meaning of §20(a) of the Exchange Act. Therefore, the Individual Defendants are jointly and severally liable for the Company's fraud, as alleged herein.

343. The Individual Defendants controlled and had the authority to control the content of the Company's SEC statements and press releases. Because of their close involvement in the everyday activities of the Company, and because of their wide-ranging supervisory authority, the Individual Defendants reviewed or had the opportunity to review these documents prior to their issuance, or could have prevented their issuance or caused them to be corrected.

344. The Individual Defendants knew or recklessly disregarded the fact that Insys's representations were materially false and misleading and/or omitted material facts when made. In so doing, the Individual Defendants did not act in good faith.

345. By virtue of their high-level positions and their participation in and awareness of Insys's operations and public statements, the Individual Defendants were able to and did influence and control Insys's decision-making, including controlling the content and dissemination of the documents that Plaintiff and the Class contend contained materially false and misleading information and on which Plaintiff and the Class relied.

346. The Individual Defendants had the power to control or influence the statements made giving rise to the securities violations alleged herein, and as set forth more fully above.

347. As set forth herein, the Individual Defendants each violated §10(b) of the Exchange Act and Rule 10b-5, thereunder, by their acts and omissions as alleged herein. By virtue of their positions as controlling persons, the Individual Defendants are also liable pursuant to §20(a) of the Exchange Act.

348. As a direct and proximate result of the Individual Defendants' wrongful conduct, Plaintiff and the Class suffered damages in connection with their purchase of Insys securities.

349. This action was filed within two years of discovery of the fraud and within five years of Plaintiff's purchases of securities giving rise to the cause of action.

**PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiff prays for relief and judgment, as follows:

- A. Declaring this action to be a proper class action pursuant to Rule 23 of the Federal Rules of Civil Procedure and certifying Plaintiff as representatives of the Class;
- B. Awarding Plaintiff and the members of the Class damages, including interest;
- C. Awarding Plaintiff reasonable costs and attorneys' fees; and
- D. Awarding such other relief as the Court may deem just and proper.

**JURY DEMAND**

In accordance with Fed. R. Civ. P. 38(b), Plaintiff demands a jury trial of all issues involved, now, or in the future, in this action.

Dated: October 27, 2017

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/s/ *Shannon L. Hopkins*

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